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(54) Title: CLOSURE DEVICES, SYSTEMS, AND METHODS

(57) Abstract: The present disclosure includes vessel closure devices, systems, and methods. A closure system configured to close a body lumen opening may include a handle member. A tube set configured to deliver and/or deploy a closure element may be coupled to the handle member. The closure system may also include an inner lumen with an anchor member at least partially disposed in the inner lumen. A plunger member may be movably coupled to the handle member.



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CLOSURE DEVICES, SYSTEMS, AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Patent Application Serial No. 12/684,400, entitled "Closure Devices, Systems, and Methods," filed January 8, 2010, which claims the benefit of and priority to U.S. Provisional Patent Application Serial No. 61/143,751, entitled "Vessel Closure Devices and Methods," filed January 9, 2009, the disclosures of which are incorporated herein by reference in their entireties.

BACKGROUND

1. Technical Field

The present disclosure relates generally to medical devices and their methods of use. In particular, the present disclosure relates to vessel closure systems and devices and corresponding methods of use.

2. The Technology

Catheterization and interventional procedures, such as angioplasty or stenting, generally are performed by inserting a hollow needle through a patient's skin and tissue into the vascular system. A guidewire may be advanced through the needle and into the patient's blood vessel accessed by the needle. The needle is then removed, enabling an introducer sheath to be advanced over the guidewire into the vessel, e.g., in conjunction with or subsequent to a dilator.

A catheter or other device may then be advanced through a lumen of the introducer sheath and over the guidewire into a position for performing a medical procedure. Thus, the introducer sheath may facilitate introducing various devices into the vessel, while minimizing trauma to the vessel wall and/or minimizing blood loss during a procedure.

Upon completing the procedure, the devices and introducer sheath would be removed, leaving a puncture site in the vessel wall. Traditionally, external pressure would be applied to the puncture site until clotting and wound sealing occur; however, the patient must remain bedridden for a substantial period after clotting to ensure closure of the wound. This procedure may also be time consuming and expensive, requiring as much as an hour of a physician's or nurse's time. It is also uncomfortable for the patient and requires that the patient remain immobilized in the operating room, catheter lab, or holding area. In addition, a risk of hematoma exists from bleeding before hemostasis

occurs. Although some closure systems may be available, they provide limited control to flexibility to the operator, which may lead to improper or undesirable closure of the puncture site.

BRIEF SUMMARY

5 The present disclosure can include a closure system. In one embodiment, the closure system can include a handle member, a tube set, an inner lumen disposed at least partially within the tube set, a plunger member movably coupled to the handle member, and an anchor member at least partially disposed within the inner lumen. In a further embodiment, the anchor member can include an anchor portion and an elongate portion.
10 The anchor portion can be disposed in the inner lumen in an initial configuration and configured to move to an expanded configuration once deployed from the inner lumen.

 The present disclosure can also include a method of closing a body lumen opening. In one embodiment, the method can include advancing a closure system at least partially into a body lumen opening. The closure system can include a handle member, a
15 tube set configured to deliver and/or deploy a closure element, an inner lumen disposed at least partially within the tube set, a plunger member movably coupled to the handle member, and an anchor member at least partially disposed within the inner lumen. In a further embodiment, the anchor member can include an anchor portion and an elongate portion, the anchor portion being disposed in the inner lumen in an initial configuration
20 and configured to move to an expanded configuration once deployed from the inner lumen. The method can also include deploying the anchor portion of the anchor member within the body lumen. In further embodiments, the method can include positioning the anchor portion of the anchor member against a distal surface of the lumen wall proximate the body lumen opening. In yet further embodiments, the method can include advancing
25 the tube set in a distal direction to position the distal end of the tube set against a proximal surface of the lumen wall proximate the body lumen opening. In addition, the method can include deploying a closure element into the lumen wall proximate the body lumen opening to close the body lumen opening.

 In a yet further embodiment, the present disclosure can include an anchor
30 member. In one embodiment, the anchor member can include an elongate portion having a distal end and proximal end. In addition, the anchor member can include an anchor portion coupled to the distal end of the elongate portion. In a yet further embodiment, the anchor portion is configured to move elastically between an initial configuration and an

expanded configuration. The expanded configuration can include a plurality of projections.

These and other advantages and features of the present disclosure will become more fully apparent from the following description and appended claims, or may be
5 learned by the practice of the disclosure as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify at least some of the advantages and features of the present disclosure, a more particular description of the disclosure will be rendered by reference to
10 specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only illustrated embodiments of the disclosure and are therefore not to be considered limiting of its scope. The disclosure will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

15 Figure 1 discloses a closure system in accordance with one example embodiment;
Figures 2A-2D disclose an example method of operating the closure system of Figure 1 in accordance with a further embodiment;

Figures 3A-3B disclose an example anchor member in accordance with a yet further embodiment;

20 Figures 4A-4B disclose an example anchor member in accordance with an additional example embodiment;

Figures 5A-5D disclose an example method of operating the anchor member of Figures 3A-3B in accordance with one embodiment;

25 Figures 6A-6G disclose an example method of closing a body lumen opening in accordance with a further embodiment;

Figures 7A-7G disclose the operation of an example tube set; and

Figure 8 discloses an exploded view of an additional example closure system in accordance with a further embodiment.

It should be noted that the figures are not drawn to scale and that elements of
30 similar structures or functions are generally represented by like reference numerals for illustrative purposes throughout the figures. It also should be noted that the figures are only intended to facilitate the description of example configurations of the present disclosure.

DETAILED DESCRIPTION

The present disclosure relates to devices, systems, and methods for closing an opening in a body lumen. In one example embodiment, a closure system of the present disclosure may allow an operator to quickly and efficiently close a body lumen opening while simultaneously providing the operator with a greater measure of control and flexibility in positioning and anchoring the closure system than previously available. For example, the closure system may allow an operator to achieve a more intimate securement of a closure element in the tissue surrounding a body lumen opening. In a yet further embodiment, the closure system may be compatible with a wider range of body lumen wall thicknesses, thereby taking into account the possibility of calcifications or scar tissue in the lumen wall. In addition, the closure system may be configured to advance into a body lumen opening over a guidewire. Furthermore, the closure system may be compatible with a variety of sizes of body lumen openings and tissue tracts.

Embodiments of the disclosure further relate to a device closure system with a removable anchor. In one example, the anchor can be deployed from a contracted state to an expanded state. When in the expanded state, the anchor can be used to locate an opening in a vessel (e.g., an arteriotomy) when deploying, for example, a closure element, such as a clip or staple. The anchor, in conjunction with a tube set in the closure system, may sandwich the tissue surrounding the opening in the vessel. This effectively locates the opening and aids in effective and proper deployment of the closure element.

The closure system may then retract or remove the anchor during use of the closure system, leaving the arteriotomy or opening at least substantially closed or sealed by the closure element. During removal, the anchor can deform without dislodging the closure element. More specifically in one embodiment, the anchor is withdrawn back into the tube set and into the pre-deployed state. Thus, the closure system and close an opening in a body lumen using a removable anchor.

Reference is now made to Figure 1 which illustrates a closure system 100 in accordance with an implementation of the present disclosure. The closure system 100 may be configured to close an opening in a body lumen. The closure system 100 may include a handle member 110, a tube set 120 coupled to the handle member 110, a plunger member 130, an inner lumen 140, and an anchor member 150 disposed at least partially within the inner lumen 140. An operator, such as a physician, may utilize the closure system 100 and the elements thereof to close an opening in a body lumen. For example, as will be explained in more detail below, the plunger member 130 may be used

to deploy the anchor member 150 to locate the distal surface of a lumen wall and position the closure system 100 relative to a body lumen opening. Thereafter, the handle member 110 and tube set 120 may be used to deliver a closure element, such as a clip or staple, and deploy the closure element into the tissue of the body lumen wall to close or
5 substantially close the body lumen opening.

The handle member 110 of the closure system 100 may be configured to assist an operator, such as a physician, to grip, manipulate, advance, and/or operate the closure system 100 in order to close a body lumen opening. In particular, the handle member 110 may have a shape and size that conforms to the shape and size of a human hand. The
10 handle member 110 may also include a number of indentations 112 configured to at least partially receive the fingers and/or thumbs of the operator. The indentations 112 may assist the operator to grip and manipulate the handle member 110 and closure system 100. The handle member 110 may also include one or more flanges 114 to assist an operator to grip, advance, and/or retract the handle member 110 and/or closure system 100.

The handle member 110 may also include any number of mechanisms necessary to deploy a closure element. For example, the handle member 110 may include a button 116 operatively associated with one or more mechanisms configured to deploy a closure element. The button 116 may be positioned in or proximate to one of the one or more indentations 112. In a further embodiment, the button 116 may be operatively associated
15 with one or more elements of the tube set 120 configured to deploy the closure element 100. As a result, an operator may depress the button 116 in order to push, fire, or eject a closure element from the tube set 120 into the tissue of a body lumen to close a body lumen opening.

In a further embodiment, the handle member 110 may include a recess 118
25 configured to receive at least a portion of the plunger member 130. The recess 118 may be further configured to allow the plunger member 130 to move in a longitudinal direction relative to the handle member 110. In particular, the recess 118 may allow the plunger member 130 to move both distally and proximally relative to the handle member 110. For example, the recess 118 may have a cross-sectional shape similar to, but slightly
30 larger than, the cross sectional shape of the plunger member 130. As a result, the plunger member 130 may slide into and out of the recess 118 to move relative to the handle member 110.

The handle member 110 may include any number of rigid or semi-rigid materials. For example, the handle member 110 may include any number of polymers, plastics, metals, composites, other similar materials, or combinations thereof.

5 The tube set 120 may be coupled to and/or partially disposed within the handle member 110. The tube set 120 may have a proximal end 122 coupled to the handle member 110 and opposite a distal end 124. The tube set 120 may be configured to contain, deliver, and/or deploy a closure element. In particular, the tube set 120 may include one or more tubular members and/or other mechanisms configured to house, advance, push, fire, and/or eject the closure element. For example, the tube set 120 may include a pusher tube, a garage tube, a carrier tube, and/or other similar elements. In one
10 embodiment, the tube set 120 may include a spring-loaded pusher member configured to deploy the closure element when released or activated. Some example tube sets are disclosed in Figures 7-8 and described in more detail below.

The closure element may be disposed within the tube set 120 in an initial, open
15 configuration and may be configured to be deployed from the tube set 120 and move to a deployed, closed configuration. In particular, in one embodiment, the closure element may store sufficient energy, while in its initial, open configuration, to engage the tissue of and close an opening in a lumen wall. For example, the closure element may include any of a number of shape memory and/or superelastic materials and may be set to elastically
20 return to a deployed, closed configuration from any other configuration. In one embodiment, the closure element may include nitinol. In a further embodiment, the closure element may be a clip, staple, or other closure element.

The closure system 100 may also include an inner lumen 140. The inner lumen 140 may be disposed at least partially within the tube set 120, the handle member 110, and/or the plunger member 130. In a further implementation, the inner lumen 140 may be
25 movable, such as slidable, with respect to the tube set 120, the handle member 110, and/or the plunger member 130. As a result, the inner lumen 140 may move either distally or proximally relative to the tube set 120, the handle member 110, and/or the plunger member 130.

30 The inner lumen 140 may be configured to house and deliver the anchor member 150 to or away from a body lumen opening. In a further embodiment, the inner lumen 140 may be integrated into or replaced by an element of the tube set 120. The inner lumen 140 may include any number of flexible or semi-rigid materials. For example, the

inner lumen may include one or more polymers, elastomers, plastics, metals, composites, other similar materials, or combinations thereof.

As introduced above, the closure system 100 may include an anchor member 150. The anchor member 150 may be configured to locate, position the closure system 100 relative to, and/or anchor the tissue surrounding a body lumen opening. The anchor member 150 may include an anchor portion 152 and an elongate portion 154. The anchor portion 152 may be configured to be positioned and/or anchored against the distal surface of a lumen wall. The elongate portion 154 may be coupled to the anchor portion 152 and may be configured to control, deploy, position, stabilize, and/or retract the anchor portion 152. In particular, the elongate portion 154 may extend away from the anchor portion 152 in a proximal direction through the inner lumen 140, the tube set 120, the handle member 110, and/or the plunger member 130. In a further embodiment, the elongate portion 154 may be coupled at its proximal end 122 to the plunger member 130. In a yet further embodiment, the elongate portion 154 may be selectively detachable from and recouplable to the plunger member 130.

The anchor portion 152 of the anchor member 150 may be disposed in an initial, contracted configuration within the inner lumen 140. The elongate portion 154 of the anchor member 150 may extend proximally from the anchor portion 152 to the plunger member 130. In addition, the elongate portion 154 may transfer forces from the plunger member 130 to the anchor portion 152. Accordingly, by advancing the plunger member 130 or elongate portion 154 in a distal direction relative to the inner lumen 140 an operator may deploy the anchor portion 152 of the anchor member 150 from the distal end of the inner lumen 140. Retracting the plunger member 130 in a proximal direction may position and/or anchor the anchor portion 152 against a distal surface of a lumen wall. In a further embodiment, further retracting the plunger member 130 in a proximal direction may retract the anchor portion 152 of the anchor member 150 from the body lumen and/or into the inner lumen 140 or tube set 120.

The anchor portion 152 of the anchor member 150 may be configured to move from an initial, contracted configuration within the inner lumen 140 to a deployed, expanded configuration once deployed from the inner lumen 140. To facilitate movement from an initial, contracted configuration to a deployed, expanded configuration, the anchor portion 152 of the anchor member 150 may include one or more superelastic or shape memory materials such as shape memory alloys. For example, and as will be explained in more detail below, the anchor portion 152 be heat set in a deployed,

expanded configuration. The anchor portion 152 may then be elastically deformed into an initial, contracted configuration contracted and disposed within the inner lumen 140. In its initial, contracted configuration, the anchor portion 152 may store sufficient energy to return to its deployed, expanded configuration once released from the inner lumen 140.

5 In one embodiment, a user may operate the plunger member 130 to deploy and/or retract the anchor member 150. For example, the plunger member 130 may be configured to at least partially receive the tube set 120 and/or the inner lumen 140. In a further embodiment, the plunger member 130 may also be configured to receive a portion of the anchor member 150 and/or a guidewire. In a further embodiment, the inner lumen 140
10 and/or anchor member 150 may be coated to minimize friction within the inner lumen 140 to ease deployment.

The proximal end 122 of the plunger member 130 may be configured to be gripped and/or operated by an operator such as a physician. For example, an operator may grip the handle member 110 with a first hand and grip the proximal end of the
15 plunger member 130 with a second hand in order to advance or retract the plunger member 130 relative to the handle member 110. As a result, the operator may deploy the anchor portion 152 of the anchor member 150 from the inner lumen 140 and/or position the anchor portion 152 against a distal surface of a lumen wall thereby locating the body lumen opening to be closed.

20 Thereafter, the operator may advance the handle member 110 in a distal direction relative to the plunger member 130 and inner lumen 140 to position the distal end 124 of the tube set 120 against a proximal surface of the lumen wall. By so doing, the operator may facilitate the closure of the body lumen opening by at least partially gripping, sandwiching, and/or immobilizing the tissue surrounding the body lumen opening. The
25 operator may then deploy a closure element into the tissue of the lumen wall to close the body lumen opening.

The shape of the plunger member 130 may correspond with the shape of the recess 118 to facilitate relative movement between the handle member 110 and the plunger member 130. For example, the cross sectional shape of both the plunger member
30 130 and the recess 118 may be any shape desired such as circular, triangular, rectangular, or other shapes, or combinations thereof. In addition, the length of the plunger member 130 and the corresponding depth of the recess 118 may be any length and depth desired to allow sufficient relative movement between the plunger member 130 and handle member 110. For example, the length of the plunger member 130 and the corresponding depth of

the recess 118 may be sufficient to allow deployment of the anchor portion 152 from the inner lumen.

In a further embodiment, the closure system 100 may include a self-tensioning mechanism configured to automatically provide tension in the anchor member 150 once the anchor portion 152 has deployed. For example, in one embodiment, the handle member 110 may include a spring mechanism disposed in the recess 118 and configured to resist and/or counteract movement of the plunger member 130 in a distal direction relative to the handle member 110. In particular, advancing the plunger member 130 in a distal direction relative to the handle member 110 may transfer energy to the spring mechanism, which may be released once the operator releases the plunger member 130.

As a result, the spring mechanism may move the plunger member 130 in a proximal direction relative to the handle member 110 thereby retracting the anchor portion 152 in a proximal direction, thereby automatically engaging the distal surface of a lumen wall, and/or advancing the handle member 110 and tube set 120 in a distal direction, thereby engaging the proximal surface of the lumen wall. The spring mechanism can also create sufficient tension within the anchor member 150 to produce a desired pressure on the tissue of the lumen wall between the anchor portion 152 and the tube set 120. Accordingly, the closure system 100 may automatically and efficiently create the desired sandwiching or immobilizing force on the tissue surrounding the body lumen opening. In addition, the spring mechanism may make it unnecessary for the operator to provide the movement or force necessary to position the closure system 100 relative to the body lumen opening. In additional embodiments, any other self-tensioning mechanism may be included in the closure system 100 to produce to desired tension in the anchor member 150 and force upon the tissue surrounding the body lumen opening. In a yet further embodiment, the plunger member 130 and closure system 100 may have a click or ratchet function similar to that of a “click” pen.

In a yet further embodiment, the closure system 100, or the elements thereof, may include a mechanism for determining the thickness of a lumen wall and/or the distance between the anchor portion 152 and the distal end 124 of the tube set 120. For example, the plunger member 130 may have a plurality of indicator lines along the length thereof. The indicator lines may be positioned and marked to indicate the position of the deployed anchor portion 152 relative to the distal end 124 of the tube set 120. In particular, the number of indicator lines exposed as the plunger member 130 is retracted may indicate the thickness of the tissue surrounding the body lumen opening being closed. The

indicator lines may be calibrated so that they read zero thickness when the anchor portion 152 is position directly against the distal end 124 of the tube set 120. As a result, the operator may refer to the indicator lines to determine the position of the anchor portion 152 relative to the distal end 124 of the tube set 120 and/or the thickness of the tissue surrounding a body lumen opening.

Additionally, the closure system 100 may incorporate at least one component of the closure systems 600 and 800, tube sets 720 and 820, and anchor members 350, 450, 550, and 650 described in connection with Figures 3-6G, respectively.

Reference is now made to Figures 2A-2D, which illustrate an example method of operating the closure system 100 of Figure 1. In particular, Figure 2A illustrates the closure system 100 in an initial configuration. In this initial configuration, the plunger member 130 may be fully retracted relative to the handle member 110, and the anchor portion 152 of the anchor member 150 may be disposed within the inner lumen 140. Advancing the plunger member 130 in a distal direction relative to the handle member 110, the tube set 120, and the inner lumen 140 may deploy the anchor portion 152 of the anchor member 150 from the inner lumen 140, as shown in Figure 2B. As a result, the anchor portion 152 may move from an initial, contracted configuration to a deployed, expanded configuration. In a further implementation, the plunger member 130 may include two or more plunger components. For example, the plunger member 130 may include a first component configured to deploy and/or retract the anchor member 150 and a second component configured to advance and/or retract the inner lumen 140. In a yet further implementation, the first and second components of the plunger member 130 may be movable with respect to one another.

Thereafter, retracting the plunger member 130 in a proximal direction relative to the handle member 110, the tube set 120, and/or the inner lumen 140 may retract the anchor portion 152 in a proximal direction, as shown in Figure 2C. As shown in Figure 2D, advancing the handle member 110 in a distal direction relative to the plunger member 130 may advance the tube set 120 in a distal direction until the distal end 124 of the tube set 120 is proximate the anchor portion 152 of the anchor member 150. As a result, an operator of the closure system 100 may locate, anchor, and/or immobilize the tissue surrounding a body lumen opening between the tube set 120 and anchor portion 152. Thereafter, the operator may deploy a closure element into the body lumen surrounding the body lumen opening to close the body lumen opening.

Reference is now made to Figures 3A-3B, which disclose an example anchor member 350 in accordance with implementations of the present disclosure. The example anchor member 350 of this configuration may be functionally similar to the example anchor member 150 previously described above and shown in Figures 1-2D in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or components are given like reference numerals. Additionally, the anchor member 350 may incorporate at least one component of the anchor members 450, 550, and 650 described in connection with Figures 4-6G, respectively.

The anchor member 350 may be configured to assist an operator to locate, anchor, immobilize, and/or support a body lumen opening and/or the surrounding tissue of the lumen wall. The anchor member 350 may include an anchor portion 352 and an elongate portion 354. The anchor portion 352 may include any size and/or shape configured to anchor against a surface of a lumen wall or to locate a body lumen opening. For example, the anchor portion may include a plurality of projections 356 configured to engage the tissue of a lumen wall. The projections 356 may be shaped, positioned, and/or oriented in any configuration desired to provide positioning or anchoring support. The anchor portion 352 may include any number of projections 356 desired. In the embodiment shown in Figures 3A-3B the anchor portion 352 of the anchor member 350 includes four projections 356, however, the anchor portion 352 may have fewer or more projections 356 than four.

In one embodiment, the projections may extend in a direction or a plane substantially perpendicular to the longitudinal axis of the elongate portion 354. In one configuration, the projections 356 may be rounded. In particular, the projections 356 may be leaf-shaped or pedal-shaped. In a further embodiment, the anchor portion 352 may have a shape substantially similar to a four leaf clover.

The anchor portion 352 may be coupled to the distal end of the elongate portion 354. The elongate portion 354 may include one or more elongate members 358. The elongate member(s) 358 may be configured to advance, retract, position, and/or deploy the anchor portion 352. In particular, the elongate member(s) 358 may be longitudinally rigid or semi-rigid to facilitate advancing or retracting the anchor portion 352. In one embodiment, the elongate member(s) 358 may have a solid configuration such as a nitinol

wire or a mandrel. In further embodiments, the elongate member(s) 358 may have a generally tubular configuration.

The anchor portion 352 and/or elongate portion 354 may include any number of materials. In one embodiment, the anchor portion 352 may include the same materials as the elongate portion 354. In a further embodiment, the anchor portion 352 may include different materials than the elongate portion 354.

In one embodiment, the anchor portion 352 and elongate portion 354 may include a single shape memory or superelastic wire forming both the elongate portion 354 and the anchor portion 352. The wire may be set into any shape desired for the elongate portion 354 and anchor portion 352. In particular, the wire may be set in an elongate form for the elongate portion 354 and may be set with a plurality of bights or beds forming the expanded form of the anchor portion 352. As shown in Figures 3A-3B, in one configuration, the wire may form a plurality of projections 356.

The anchor portion 352 may be configured to elastically deform to any shape and then return to its expanded shape illustrated Figures 3A-3B once released. For example, the anchor portion 352 may be elastically deformed into an elongate and/or contracted configuration and disposed within a lumen. While in this contracted configuration, the anchor portion 352 may store sufficient energy to return to its expanded configuration. Once the anchor portion 352 is deployed from the lumen, the anchor portion 352 may release the stored energy and return to its expanded configuration.

In a further embodiment, the anchor portion 352 of the anchor member 350 may include one or more gripping elements along a proximal surface. The gripping elements may be configured to provide a frictional or immobilizing force on tissue surrounding a body lumen opening. For example, the anchor portion 352 may include a plurality of ridges or teeth along a proximal surface configured to engage and grip or immobilize the tissue surrounding a body lumen opening.

Reference is now made to Figures 4A-4B, which illustrate an additional anchor member 450 in accordance with a further embodiment of the present disclosure. The example anchor member 450 of this configuration may be functionally similar to the example anchor members 150 and 350 previously described above and shown in Figures 1-3B in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or components are given like reference numerals. Additionally, the anchor

member 450 may incorporate at least one component of the anchor members 550 and 650 described in connection with Figures 5A-6G, respectively.

In one embodiment, the anchor member 450 may include an anchor portion 452 and an elongate portion 454. The anchor portion 452 may include a plurality of
5 projections 456 extending substantially perpendicular to the longitudinal axis of the elongate portion 454. As shown, the anchor portion 452 may include a figure-8 shape having two projections 456. However, the anchor portion 452 may be configured to have any desired shape and/or size having any number of projections.

The elongate portion 454 may include one or more elongate members 458. In one
10 embodiment, the elongate member(s) 458 and anchor portion 452 may be part of a single continuous piece of shape memory or superelastic wire. For example, the wire may extend along the elongate portion 454 and may form the projections 456 of the anchor portion 452 and then may terminate or alternatively extend again along the elongate portion 454. In a further embodiment, portions of the wire may overlap itself or cross
15 over in forming the anchor portion 452. The overlaps or crosses of the wire may provide better resistance against collapse or more support to the anchor portion 452.

Reference is now made to Figures 5A-5D, which illustrate a method of deploying and retracting an anchor member 550. The example anchor member 550 of this configuration may be functionally similar to the example anchor members 150, 350, and
20 450 previously described above and shown in Figures 1-4B in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or components are given like reference numerals. Additionally, the anchor member 550 may incorporate at
25 least one component of the anchor member 650 described in connection with Figures 6A-6G.

In particular, Figure 5A illustrates the anchor member 550 disposed within a lumen 540 in an initial, contracted configuration. As shown, the anchor member 550 may include an elongate portion 554 and an anchor portion 552. The elongate portion 554
30 may include a plurality of elongate members 558, such as a first elongate member 558A and a second elongate member 558B.

As shown in Figure 5B advancing the elongate portion 554, such as one or both of the elongate members 558, in a distal direction relative to the lumen 540 may deploy the anchor portion 552 from the distal end of the lumen 540. As a result, the anchor portion

552 may move from an initial, contracted configuration to a deployed, expanded configuration. In one embodiment, the deployed, expanded configuration may include a plurality of projections 556. In a further embodiment, retracting the elongate portion 554 in a proximal direction may provide an anchoring force. For example, retracting the elongate members 558 may anchor the anchor portion 552 against the distal surface of a lumen wall or any other surface against which the anchor portion 552 is positioned, as shown in Figure 5C. In one embodiment, retracting both elongate members 558 simultaneously may produce tension or some other force in the anchor portion 552 which may increase the resistance of the anchor portion 552 to contracting. For example, the tension of both elongate members 558 may be simultaneously transferred to the anchor portion 552 thereby creating sufficient tension in the anchor portion 552 to resist movement by the anchor portion 552 away from its expanded configuration. In addition, providing an opposing force against a proximal surface of the anchor portion 552, such as with the lumen wall, may also assist in creating sufficient tension in the anchor portion 552 to resist contraction of the anchor portion 552. In a further implementation, the wires of the anchor portion 552 may overlap or cross over each other in order to increase resistance.

As shown in Figure 5D, retracting only one elongate member, such as the first elongate member 558A, may lessen the tension in the anchor portion 552, thereby allowing the anchor portion to move from its deployed, expanded configuration to a contracted configuration. As a result, by retracting only the first elongate member 558A, without applying tension to the second elongate member 558B or with applying a distal force to the second elongate member 558B, the anchor portion 552 may contract and be retracted into the lumen 540. In further implementations, by retracting only the second elongate member 558B, without applying tension to the first elongate member 558A or with applying a distal force to the first elongate member 558A, the anchor portion 552 may contract and/or be retracted into the lumen 540.

Reference is now made to Figures 6A-6G, which illustrate a method of closing a body lumen opening using a closure system 600. The example anchor member 650 of this configuration may be functionally similar to the example anchor members 150, 350, 450, and 550 previously described above and shown in Figures 1-5D in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or

components are given like reference numerals. In addition, the closure system 600 may incorporate at least one element of the tube set 720 of Figures 7A-7G or closure system 800 of Figure 8.

As shown in Figure 6A, the closure system 600 may be at least partially advanced
5 into a body lumen opening. For example, after completing a percutaneous medical procedure, an operator may advance the closure system 600 over a guidewire 660 through a tissue tract 680 and through a body lumen opening 675 in a lumen wall 670. In particular, the operator may advance the closure system 600 until the inner lumen 640 of the closure system 600 extends at least partially into the body lumen 690. Once the
10 closure system 600 has been advanced at least partially into the body lumen 690 the operator may then retract the guidewire 660 from the body lumen 690.

As shown in Figure 6B, once the closure system 600 is advanced into the body lumen 690, the operator may deploy the anchor member 650 into the body lumen 690. As explained in more detail above, the operator may deploy the anchor member 650 by
15 advancing the plunger member 630 and/or elongate portion 654 in a distal direction relative to the handle member 610, the tube set 620, and the inner lumen 640. Once deployed from the inner lumen, the anchor portion 652 of the anchor member 650 may move from an initial, contracted configuration to a deployed, expanded configuration. As shown in Figure 6C, once the anchor portion 652 of the anchor member 650 has been
20 deployed within the body lumen 690, the operator may retract the plunger member 630 and/or closure system 600 to position the anchor portion 652 of the anchor member 650 against the distal surface of the lumen wall 670 proximate the body lumen opening as also shown in Figure 6C'. In particular, the operator may retract the plunger member 630 and/or closure system 600 until she feels the anchoring force or resistance from the
25 anchor portion 652 of the anchor member 650 against the distal surface of the lumen wall 670 thereby locating the body lumen opening 675 and anchoring or securing the tissue surrounding the body lumen opening 675. As shown, the anchor portion 652 may include a plurality of projections 656 which engage and anchor the tissue of the lumen wall 670. In particular, the projections 656 may extend in a direction substantially perpendicular to the longitudinal axis of the elongate portion 654, the tube set 620, and/or inner lumen
30 640.

Once the anchor portion 652 has located the body lumen opening 675 and/or anchored or secured the tissue surrounding the body lumen opening 675, the operator may advance the handle member 610 in a distal direction relative to the plunger member 630

in order to advance the tube set 620 in a distal direction relative to the anchor portion 652. In particular, the operator may advance the handle member 610 and/or tube set 620 until the distal end 624 of the tube set 620 engages the proximal surface of the lumen wall 670 proximate or surrounding the lumen opening. As a result, in one embodiment, by
5 advancing the tube set 620 in a distal direction and/or retracting the anchor portion 652 in a proximal direction, the operator may sandwich the tissue of the lumen wall 670 surrounding the body lumen opening 675 between the tube set 620 and the anchor portion 652. Accordingly, the operator may thereby engage and/or at least partially immobilize the tissue surrounding the body lumen opening 675. This may facilitate the successful
10 deployment of a closure element 695 into the tissue surrounding the body lumen opening 675, thereby, facilitating the closure of the body lumen opening 675. In particular, the tube set 620 and the anchor portion 652 may hold the tissue in place while a closure element is deployed into the tissue. Therefore, as shown in Figure 6E the operator may then deploy a closure element 695 into the tissue surrounding the body lumen opening. In
15 one embodiment, the operator may depress the button 616 to eject or deploy the closure element 695 into the lumen wall 670. In particular, the closure element 695 may be deployed from an initial, open configuration to a deployed, closed configuration, thereby, engaging and bringing the tissue surrounding the body lumen opening 675 together to close the body lumen opening 675. The closure element 695 may include any device
20 configured to close a body lumen opening 675. For example, the closure element 695 may include a staple, a clip, other similar devices, or combinations thereof.

As shown in Figure 6F, once the closure element 695 has been deployed, the handle member 610, tube set 620, and/or inner lumen 640 may be retracted out of and/or away from the body lumen 690 and tissue tract 680, as shown in Figure 6F. Thereafter,
25 the anchor member 650 may be retracted by retracting the elongate portion 654 in a proximal direction. For example, in one embodiment the anchor portion 652 may be pulled through the closure element 695. The closure element 695 may have superelastic properties to facilitate the withdrawal of the anchor portion 652 through the closure element 695. For example, the closure element may at least partially expand to facilitate
30 the withdrawal of the anchor portion 652 and then return to a contracted position to close the body lumen opening 675. Accordingly, by following one or more of the acts disclosed in Figures 6A-6G, an operator may efficiently close a body lumen opening 675 with a greater amount of flexibility and control.

In one embodiment, the inner lumen 640 can be held in place against the outer surface of the body lumen while the anchor member 650 is retracted. Holding the inner lumen 640 may provide sufficient force to allow the anchor member and more particularly the anchor portion 652 to deform into the pre-deployment state inside of the inner lumen 640. As previously stated, this may be achieved by retracting a single elongate member. This may ensure that the closure element does not become dislodged as the anchor portion 652 is withdrawn and contracted. In further embodiments, the anchor wire may be substantially smaller than the closure element. As a result, pulling the anchor portion 652 through the closure element may not affect the positioning of the closure element since the closure element anchors in the tissue by design. In one implementation, the wire of the anchor portion 652 may be superelastic with a diameter small enough to not require substantial force to collapse the anchor portion 652 and pull it through the deployed closure element. For example, the anchor wire may have a diameter of around .005-.007".

In one configuration, the anchor, closure element, and/or other aspects or components of the closure system disclosed herein can be made of a single material or of multiple materials. This can include a metal primary material and polymer/drug topcoat or a different metal top layer. The multiple layers can be resiliently flexible materials or rigid and inflexible materials, and selected combinations thereof. The use of resiliently flexible materials can provide force-absorbing characteristics, which can also be beneficial for absorbing stress and strains, which may inhibit crack formation at high stress zones. Also, the multiple layers can be useful for applying radiopaque materials. For example, types of materials that are used to make a closure element can be selected so that the closure element is capable of being in a first orientation (e.g., delivery orientation) during placement and capable of transforming to a second orientation (e.g., deploying orientation) when deployed to close the opening in a lumen.

Embodiments of the anchor, closure element and the like can include a material made from any of a variety of known suitable biocompatible materials, such as a biocompatible shape memory material (SMM). For example, the SMM can be shaped in a manner that allows for a delivery orientation while within the tube set, but can automatically retain the memory shape of the closure element once deployed into the tissue to close the opening. SMMs have a shape memory effect in which they can be made to remember a particular shape. Once a shape has been remembered, the SMM may be bent out of shape or deformed and then returned to its original shape by unloading

from strain or heating. Typically, SMMs can be shape memory alloys (SMA) comprised of metal alloys, or shape memory plastics (SMP) comprised of polymers. The materials can also be referred to as being superelastic.

Usually, an SMA can have an initial shape that can then be configured into a memory shape by heating the SMA and conforming the SMA into the desired memory shape. After the SMA is cooled, the desired memory shape can be retained. This allows for the SMA to be bent, straightened, twisted, compacted, and placed into various contortions by the application of requisite forces; however, after the forces are released, the SMA can be capable of returning to the memory shape. The main types of SMAs are as follows: copper-zinc-aluminum; copper-aluminum-nickel; nickel-titanium (NiTi) alloys known as nitinol; nickel-titanium platinum; nickel-titanium palladium; and cobalt-chromium-nickel alloys or cobalt-chromium-nickel-molybdenum alloys known as elgiloy alloys. The temperatures at which the SMA changes its crystallographic structure are characteristic of the alloy, and can be tuned by varying the elemental ratios or by the conditions of manufacture. This can be used to tune the closure element so that it reverts to the memory shape to close the arteriotomy when deployed at body temperature and when being released from the tube set.

For example, the primary material of a closure element can be of a NiTi alloy that forms superelastic nitinol. In the present case, nitinol materials can be trained to remember a certain shape, retained within the tube set, and then deployed from the tube set so that the tines penetrate the tissue as it returns to its trained shape and closes the opening. Also, additional materials can be added to the nitinol depending on the desired characteristic. The alloy may be utilized having linear elastic properties or non-linear elastic properties.

An SMP is a shape-shifting plastic that can be fashioned into a closure element in accordance with the present disclosure. Also, it can be beneficial to include at least one layer of an SMA and at least one layer of an SMP to form a multilayered body; however, any appropriate combination of materials can be used to form a multilayered device. When an SMP encounters a temperature above the lowest melting point of the individual polymers, the blend makes a transition to a rubbery state. The elastic modulus can change more than two orders of magnitude across the transition temperature (T_{tr}). As such, an SMP can be formed into a desired shape of an endoprosthesis by heating it above the T_{tr} , fixing the SMP into the new shape, and cooling the material below T_{tr} . The SMP can then be arranged into a temporary shape by force and then resume the memory shape

once the force has been released. Examples of SMPs include, but are not limited to, biodegradable polymers, such as oligo(ϵ -caprolactone)diol, oligo(p -dioxanone)diol, and non-biodegradable polymers such as, polynorborene, polyisoprene, styrene butadiene, polyurethane-based materials, vinyl acetate-polyester-based compounds, and others yet to be determined. As such, any SMP can be used in accordance with the present disclosure.

An anchor, closure element and the like may have at least one layer made of an SMM or suitable superelastic material and other suitable layers can be compressed or restrained in its delivery configuration within the garage tube or inner lumen, and then deployed into the tissue so that it transforms to the trained shape. For example, a closure element transitions to close the opening in the body lumen while an anchor may expand to anchor the closure system.

Also, the anchor, closure element, or other aspects or components of the closure system can be comprised of a variety of known suitable deformable materials, including stainless steel, silver, platinum, tantalum, palladium, nickel, titanium, nitinol, nitinol having tertiary materials (U.S. 2005/0038500, which is incorporated herein by reference, in its entirety), niobium-tantalum alloy optionally doped with a tertiary material (U.S. 2004/0158309, 2007/0276488, and 2008/0312740, which are each incorporated herein by reference, in their entireties) cobalt-chromium alloys, or other known biocompatible materials. Such biocompatible materials can include a suitable biocompatible polymer in addition to or in place of a suitable metal. The polymeric closure element can include biodegradable or bioabsorbable materials, which can be either plastically deformable or capable of being set in the deployed configuration.

In one embodiment, the closure element or anchor may be made from a superelastic alloy such as nickel-titanium or nitinol, and includes a ternary element selected from the group of chemical elements consisting of iridium, platinum, gold, rhenium, tungsten, palladium, rhodium, tantalum, silver, ruthenium, or hafnium. The added ternary element improves the radiopacity of the nitinol closure element. The nitinol closure element has improved radiopacity yet retains its superelastic and shape memory behavior and further maintains a thin body thickness for high flexibility.

In one embodiment, the anchor or closure element can be made at least in part of a high strength, low modulus metal alloy comprising Niobium, Tantalum, and at least one element selected from the group consisting of Zirconium, Tungsten, and Molybdenum.

In further embodiments, the closure element or anchor can be made from or be coated with a biocompatible polymer. Examples of such biocompatible polymeric

materials can include hydrophilic polymer, hydrophobic polymer biodegradable polymers, bioabsorbable polymers, and monomers thereof. Examples of such polymers can include nylons, poly(alpha-hydroxy esters), polylactic acids, polylactides, poly-L-lactide, poly-DL-lactide, poly-L-lactide-co-DL-lactide, polyglycolic acids, polyglycolide, 5 poly(lactic-co-glycolic acids), polyglycolide-co-lactide, polyglycolide-co-DL-lactide, polyglycolide-co-L-lactide, polyanhydrides, polyanhydride-co-imides, polyesters, polyorthoesters, polycaprolactones, polyesters, polyanhydrides, polyphosphazenes, polyester amides, polyester urethanes, polycarbonates, poly(trimethylene carbonate), polyglycolide-co-trimethylene carbonates, poly(PBA-carbonates), polyfumarates, 10 polypropylene fumarate, poly(p-dioxanone), poly(hydroxyalkanoates), polyamino acids, poly-L-tyrosines, poly(beta-hydroxybutyrate), poly(hydroxybutyrate-hydroxyvaleric acids), polyethylenes, polypropylenes, polyaliphatics, poly(vinylalcohol), poly(vinylacetates), hydrophobic/hydrophilic copolymers, alkylvinylalcohol copolymers, ethylenevinylalcohol copolymers (EVAL), propylenevinylalcohol copolymers, 15 poly(vinylpyrrolidone) (PVP), combinations thereof, polymers having monomers thereof, or the like.

Reference is now made to Figures 7A-7G, which disclose an example tube set 720. The example tube set 720 of this configuration may be functionally similar to the example tube set 120 and 620 previously described above and shown in Figures 1, 2, and 20 6A-6G in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or components are given like reference numerals. Additionally, the tube set 720 may incorporate at least one component of the tube set 820 of Figure 8. In further 25 embodiments, the tube set 720 may be utilized with the closure systems 100 and 600 disclosed in Figures 1, 2A-2D, and 6A-6G.

The tube set 720 may include a garage sheath 722, a pusher tube 724, and a carrier tube 726. In addition, the tube set 720 may be configured to receive or house a locator element and closure element 795. In one embodiment, the tube set 720 may house an 30 inner lumen 740, and/or anchor member 750. In further embodiments, the tube set 720 may be configured to deliver and/or deploy the closure element 795 in order to close an opening in a lumen wall.

The garage sheath 722 may be configured to cover, protect, and/or house the closure element 795 within the tube set 720 and/or other components of the tube set 720.

In one embodiment, the garage sheath 722 may be generally tubular in shape. In a further embodiment, the distal end of the garage sheath 722 may have a different configuration than the remainder of the garage sheath 722. For example, the distal end of the garage sheath 722 may have an inwardly tapered configuration. In further embodiments, the distal end may be configured to at least partially expand to facilitate deployment of the closure element 795. For example, the distal end of the garage sheath 722 may include one or more longitudinal slits thereby forming one or more flanges that may deflect radially outwardly in order to facilitate deployment of the closure element 795.

In addition to the garage sheath 722, the tube set 720 may include a pusher tube 724. The pusher tube 724 may be configured to deploy the closure element 795. In one embodiment, the pusher tube 724 may be generally tubular in shape along the length thereof. The pusher tube 724 may be disposed between the carrier tube 726 and the garage sheath 722 and proximal of the closure element 795. In a further embodiment, the distal end of the pusher tube 724 may include one or more fingers or projections extending from the distal end of the pusher tube 724 and configured to help stabilize and/or deploy the closure element 795. For example, the fingers or projections extending from the distal end of the pusher tube 724 may be configured in size to fit into corresponding waves, undulations, or other features along a proximal edge or surface of the closure element 795.

In addition to the pusher tube 724, the tube set 720 may include a carrier tube 726. The carrier tube 726 may be configured to carry the closure element 795 in a delivery configuration to a location proximate an opening in a body lumen. In one embodiment, the carrier tube 726 may be generally tubular in shape along the length thereof. The carrier tube 726 may be disposed at least partially within the pusher tube 724 with the closure element 795 disposed thereon. In further embodiments, the distal end of the carrier tube 726 may have a different configuration than the remainder of the carrier tube 726. For example, the distal end of the carrier tube 726 may flare radially outwards to facilitate successful deployment of the closure element 795. For example, the flared distal end of the carrier tube 726 may direct one or more elements of the closure element 795 outwards to engage tissue surrounding the opening in the body lumen to better close the body lumen opening.

The garage sheath 722, pusher tube 724, and/or carrier tube 726 may include any of a number of materials, such as biocompatible polymers and/or metals. In one example, one or more of the garage sheath 722, pusher tube 724, and/or carrier tube 726 may

include stainless steel. The materials of the garage sheath 722, pusher tube 724, and/or carrier tube 726 may have rigid, semi-rigid, or flexible mechanical properties as desired for a particular embodiment.

5 The garage sheath 722, pusher tube 724, and/or carrier tube 726 may be longitudinally movable relative to each other. The independent longitudinal movement of each element of the tube set 720 may facilitate the deployment of the closure element 795 and corresponding closure of a body lumen opening. As shown in Figure 7A, the tube set 720 may have an initial delivery configuration, in which the closure element 795 is disposed on the carrier tube 726 and the anchor member 750 is disposed within the carrier tube 726. In this initial delivery configuration, a medical care provider or user can move the tube set 720 into position within or near an opening in a body lumen.

Once the tube set 720 is in position proximate a body lumen opening, the user of the tube set 720 can advance the inner lumen 740 at least partially into the body lumen, as shown in Figure 7B. Once the inner lumen 740 is partially disposed within the body lumen, the user may advance the anchor portion 752 of the anchor 750 by advancing the elongate member(s) 754 relative to the inner lumen 740 and tube set 720. As a result, the anchor portion 752 may deploy from a delivery configuration to a deployed configuration as described in more detail above.

Once the anchor portion 752 is deployed within the body lumen, the user may retract the anchor 750 in a proximal direction to position the anchor portion 752 against the distal surface of the body lumen surrounding the opening, as shown in Figure 7C. In a further embodiment, the user can retract the garage tube 722 in order to expose the closure element 795, as shown in Figure 7D.

Once the carrier tube 726 is anchored against the body lumen, the user can deploy the closure element 795 by advancing the pusher tube 724 in a distal direction relative to the carrier tube 726, as shown in Figure 7E. As the pusher tube 724 advances, it may come into contact with the closure element 795 and begin to advance the closure element 795 in a distal direction relative to the carrier tube 726. In further embodiments, as the closure element 795 advances, the flared distal end of the carrier tube 726 may expand the closure element 795 and direct one or more tines of the closure element 795 radially outward to better engage the tissue surrounding the opening in the body lumen.

As shown in Figure 7F, the user can continue to advance the pusher tube 724 until the closure element 795 extends at least partially beyond the distal end of the carrier tube 726 and into engagement with the body lumen. Once deployed beyond the carrier tube

726, the closure element 795 may move from its expanded, delivery configuration to a deployed, collapsed configuration, thereby closing the body lumen opening, as shown in Figure 7G. In addition, the user can retract the anchor portion 752 through the deployed closure element 795, as disclosed in more detail above. In further embodiments, the user may retract the tube set 720 and anchor 750 in a proximal direction away from the body lumen and out of the tissue tract, thereby leaving the deployed closure element in place.

Reference is now made to Figure 8, which illustrates an additional example closure system 800 in accordance with a further embodiment of the present disclosure. The example closure system 800 of this configuration may be functionally similar to the example closure systems 100 and 600 and tube set 720 previously described above and shown in Figures 1, 2A-2D, 6A-6G, and 7 in most respects, wherein certain features will not be described in relation to this configuration wherein those components may function in the manner as described above and are hereby incorporated into this additional configuration described below. Like structures and/or components are given like reference numerals. Additionally, the closure systems 100 and 600 and tube set 720 may incorporate one or more components of the closure system 800.

As shown, the closure system 800 may include a handle member 810, a tube set 820 configured to couple with or be partially disposed within the handle member 810, and a plunger member 830 and firing pin 816 configured for manipulation by a user in order to operate the closure system 800 and deploy a closure element, such as a clip or staple. As a result, a user, such as a physician, may utilize the closure system 800 and the elements thereof to close an opening in a body lumen.

The handle member 810 of the closure system 800 may be configured to assist an operator, such as a physician, to grip, manipulate, advance, and/or operate the closure system 800 in order to close a body lumen opening. In one embodiment, the handle member may have an upper portion 810a and a lower portion 810b. The upper portion 810a and lower portion 810b may be connected using one or more fasteners, adhesives, welds, and/or other mechanisms. In further embodiments, the handle member may define a recess 818 configured to house one or more components of the closure system 800. The recess 818 may be configured to receive components of the tube set 820 as well as other components of the closure system 800 disclosed in Figure 8 and described in more detail below. In yet further embodiments, the recess 818 may have openings along the sides thereof configured to receive portions of the tube set 820 during operation of the closure system 800.

As shown, the closure element 800 may also include a tube set 820. In one embodiment, the tube set 820 may include a garage tube 822, pusher tube 824, and carrier tube 826. In further embodiments, each of the garage tube 822, pusher tube 824, and carrier tube 826 may include a slider block at its proximal end configured to be disposed
5 within and slide along the recess 818 of the handle member 810. Each of the slider blocks may be further configured to lock within the openings along the sides of the recess 818 to restrict or control the movement of each member of the tube set 820. For example, after moving in a distal direction to position the components of the tube set 820 for deployment of a closure element, one or more of the slider blocks may lock into the
10 openings to restrict further movement, such as in a proximal direction.

The handle member 810 may also be operatively associated with any number of mechanisms configured to deploy a closure element. For example, the handle member 810 may include a button 816 operatively associated with one or more mechanisms configured to deploy a closure element. The button 816 may be operatively associated
15 with a firing pin 817 configured to release stored energy to fire or deploy a closure element. For example, the closure system 800 may store energy in a spring 815. In one embodiment, the spring 815 may be disposed on and/or between components of the tube set 820. In further embodiments, the energy may be transferred to the spring 815 by depressing the plunger member 830. A user may release the stored energy by depressing
20 the button 816, which may release the firing pin 817. In one embodiment, the stored energy may transfer to the pusher tube 824 in order to deploy the closure element. As a result, an operator may depress the button 816 in order to push, fire, or eject a closure element from the tube set 820 into the tissue of a body lumen to close a body lumen opening.

25 The present disclosure may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the disclosure is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the
30 claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. A closure system comprising:
5 a handle member;
a tube set configured to deliver and/or deploy a closure element, the tube set having a distal end and a proximal end, the proximal end of the tube set being coupled to the handle member;
an inner lumen disposed at least partially within the tube set;
10 a plunger member movably coupled to the handle member; and
an anchor member at least partially disposed within the inner lumen, the anchor member comprising an anchor portion and an elongate portion, the anchor portion being disposed in the inner lumen in an initial configuration and configured to move to an expanded configuration once deployed from the inner lumen.
15
2. The closure system of claim 1, the plunger member being longitudinally slidable with respect to the handle member.
3. The closure system of claim 1, a closure element disposed within the tube set in an
20 initial configuration and being configured to move to a deployed configuration once deployed from the tube set.
4. The closure system of claim 1, the plunger member being at least partially
25 disposed within a recess in the handle member.
5. The closure system of claim 1, the inner lumen being movable relative to the tube set and handle member.
6. The closure system of claim 1, the anchor member comprising shape memory or
30 superelastic materials.
7. The closure system of claim 6, the anchor portion further comprising an elongate wire forming the elongate portion and anchor portion.

8. The closure system of claim 1, the expanded configuration of the anchor portion comprising a plurality of projections extending in a direction substantially perpendicular to the longitudinal axis of the elongate portion of the anchor member.

5 9. The closure system of claim 8, wherein at least one of the projections is shaped similar to a petal or leaf.

10 10. The closure system of claim 9, wherein the expanded configuration of the anchor portion is substantially similar in shape to a four-leaf clover, figure eight, a ball, or a configuration having more than four leaves.

11. The closure system of claim 1, wherein the elongate portion of the anchor member is coupled to the plunger member.

15 12. The closure system of claim 11, wherein the plunger member is configured to slide in a distal direction relative to the handle member to deploy the anchor portion of the anchor member.

20 13. The closure system of claim 12, wherein the handle member is configured to move in a distal direction relative to the plunger member to advance the distal end of the tube set to proximity with the anchor portion of the anchor member.

25 14. The closure system of claim 1, further comprising the handle member and/or tube set being configured to deploy the closure element from the distal end of the tube set.

15. The closure system of claim 1, the closure element comprising a clip or staple.

30 16. The closure system of claim 1, the handle member further comprising one or more indentations or flanges configured to facilitate gripping or manipulating the handle member.

17. The closure system of claim 1, wherein the tube set comprises a garage tube, a pusher tube, and a carrier tube.

18. A method of closing a body lumen opening comprising:

advancing a closure system at least partially into a body lumen opening, the closure system comprising:

a handle member;

5 a tube set configured to deliver and/or deploy a closure element, the tube set having a distal end and a proximal end, the proximal end of the tube set being coupled to the handle member;

an inner lumen disposed at least partially within the tube set;

a plunger member movably coupled to the handle member; and

10 an anchor member at least partially disposed within the inner lumen, the anchor member comprising an anchor portion and an elongate portion, the anchor portion being disposed in the inner lumen in an initial configuration and configured to move to an expanded configuration once deployed from the inner lumen;

15 deploying the anchor portion of the anchor member within the body lumen;

positioning the anchor portion of the anchor member against a distal surface of the lumen wall proximate the body lumen opening;

advancing the tube set in a distal direction to position the distal end of the tube set against a proximal surface of the lumen wall proximate the body lumen opening; and

20 deploying a closure element into the lumen wall proximate the body lumen opening to close the body lumen opening.

19. The method of claim 18, further comprising advancing the plunger member to
25 deploy the anchor portion of the anchor member and retracting the plunger member to retract the anchor portion of the anchor member.

20. An anchor member comprising:

an elongate portion having a distal end and proximal end; and

30 an anchor portion coupled to the distal end of the elongate portion, the anchor portion being configured to move elastically between an initial configuration and an expanded configuration, the expanded configuration comprising a plurality of projections.

21. The anchor member of claim 20, wherein the plurality of projections extend in a direction substantially perpendicular to the longitudinal axis of the elongate portion.

22. The anchor member of claim 20, the plurality of projections comprising at least 2
5 projections.

23. The anchor member of claim 20, further comprising the anchor member comprising a shape memory or superelastic wire being set in the expanded configuration.

10 24. The anchor member of claim 20, the elongate portion comprising a first elongate member and a second elongate member.

25. The anchor member of claim 24, wherein the anchor portion is configured to provide more resistance to movement from an expanded configuration to a contracted
15 configuration when tension is applied to both the first elongate member and the second elongate member than when tension is only applied to one of the first elongate member and second elongate member.

26. The anchor member of claim 20, wherein the expanded configuration is
20 substantially similar in shape to a four-leaf clover, figure eight, a ball, or a configuration having more than four leaves.

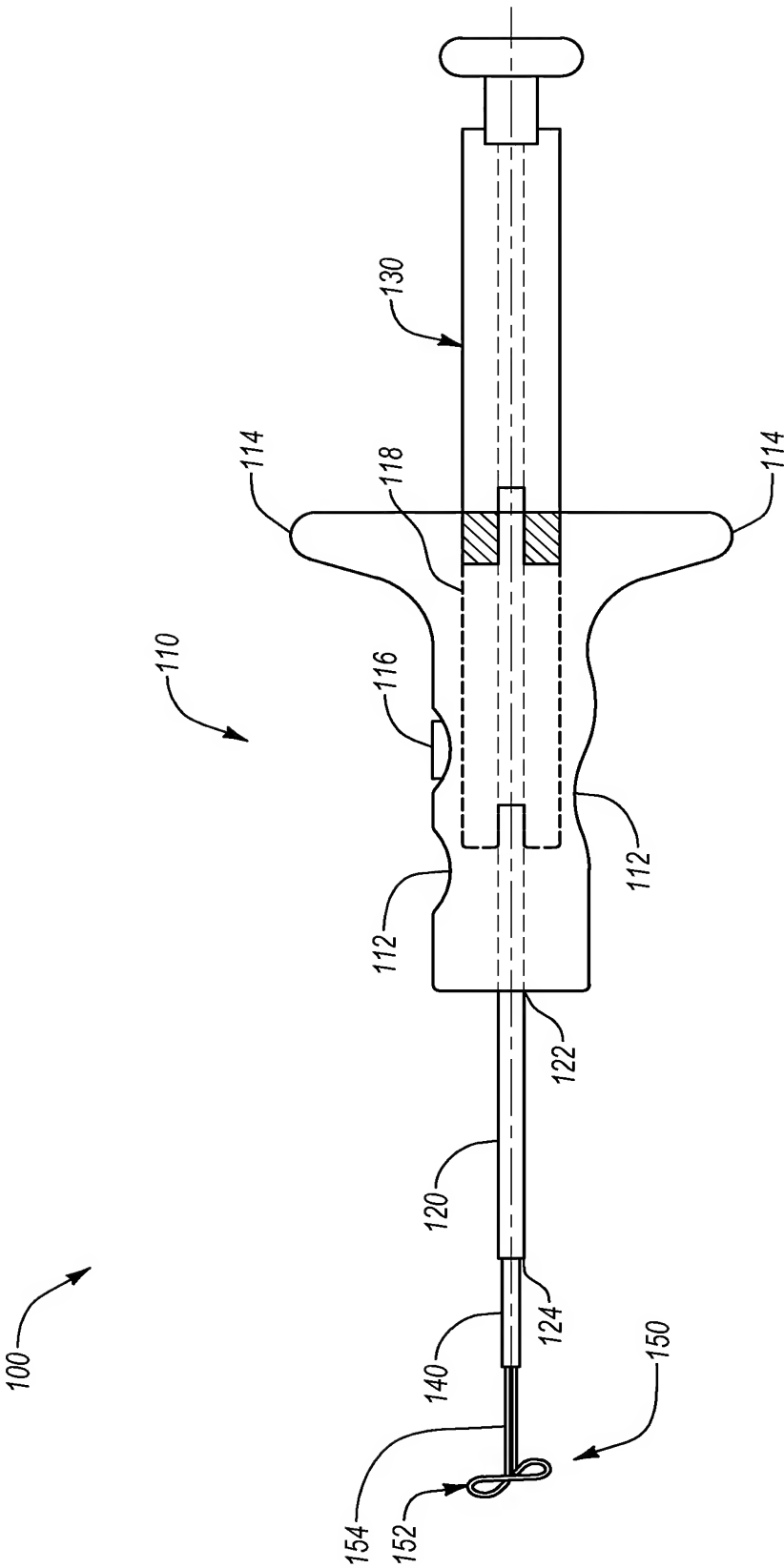
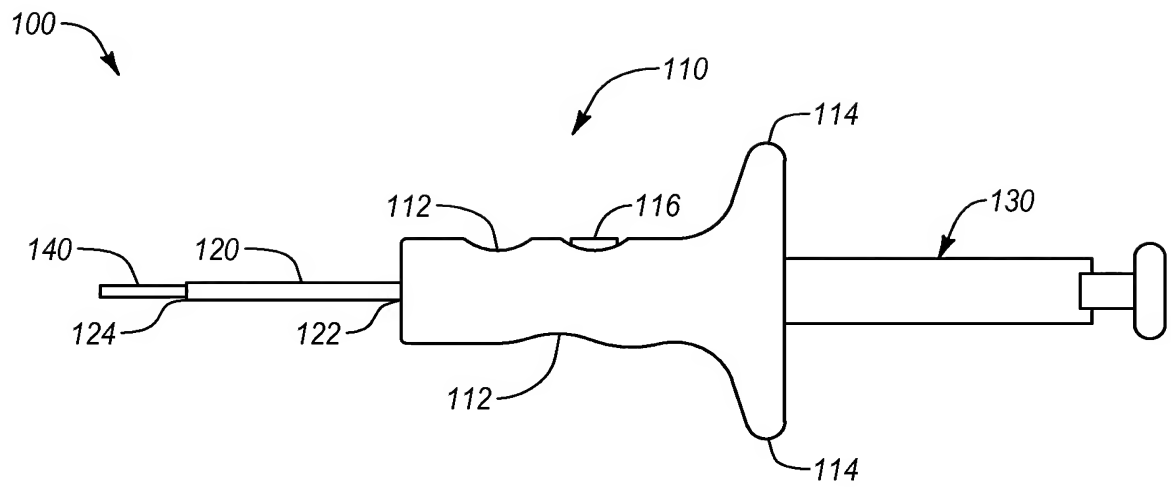
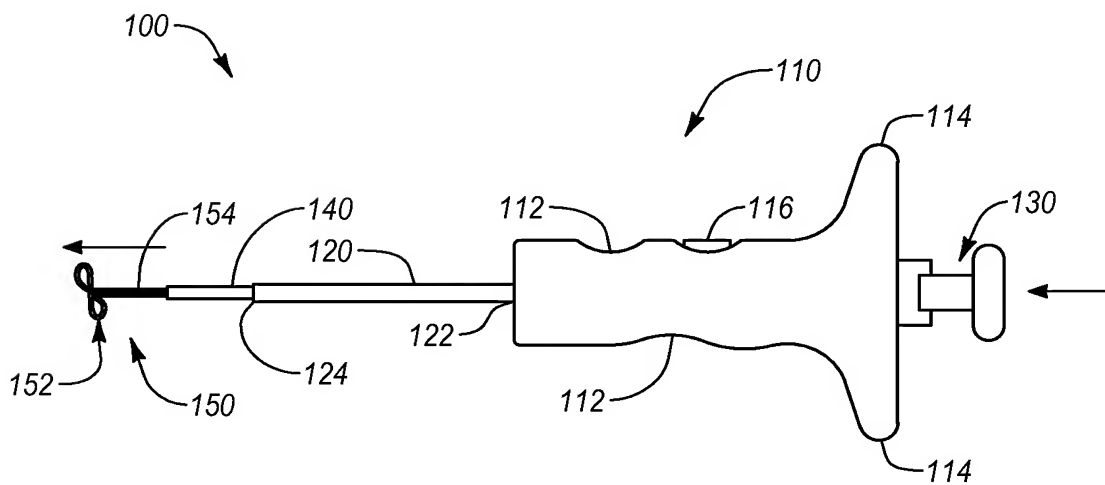


Fig. 1

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*Fig. 2A**Fig. 2B*

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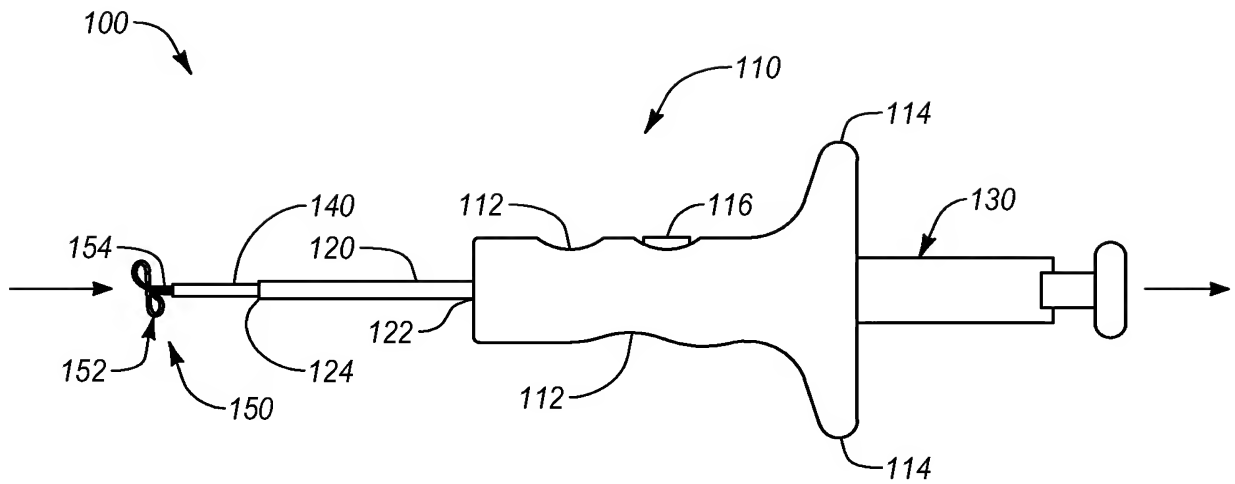


Fig. 2C

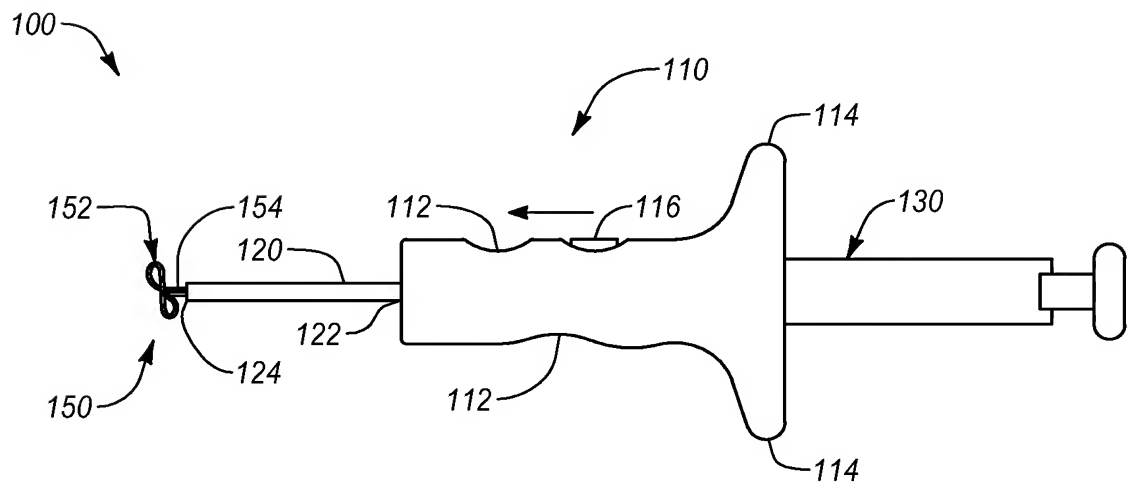


Fig. 2D

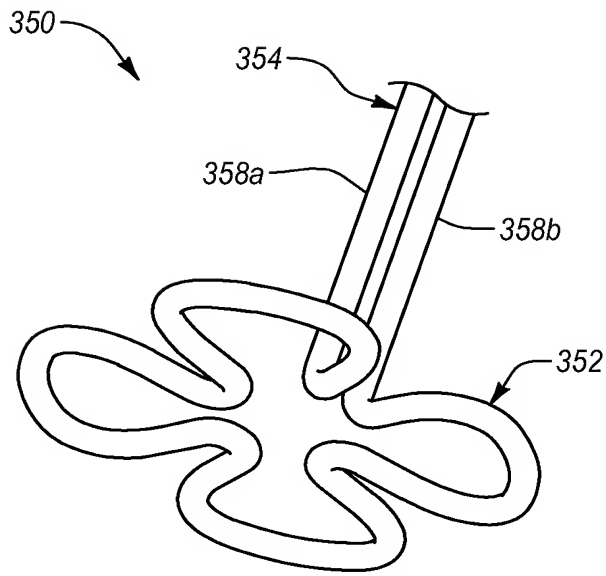


Fig. 3A

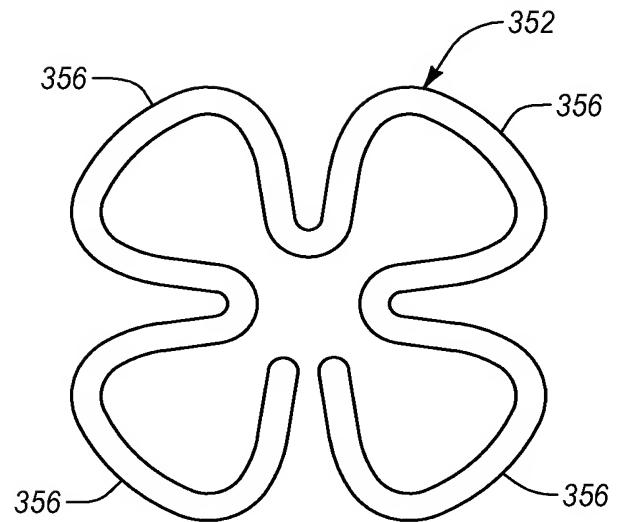


Fig. 3B

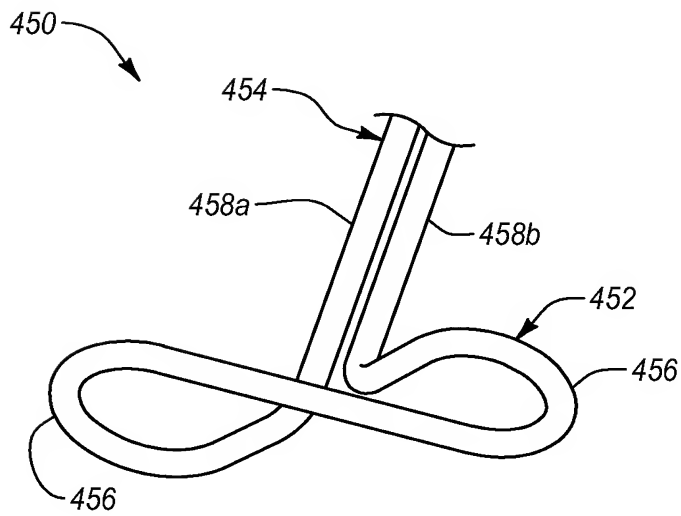


Fig. 4A

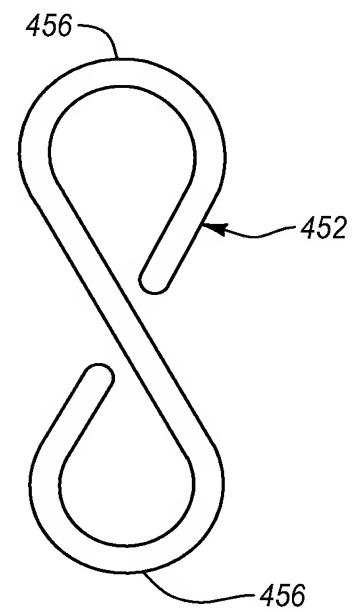


Fig. 4B

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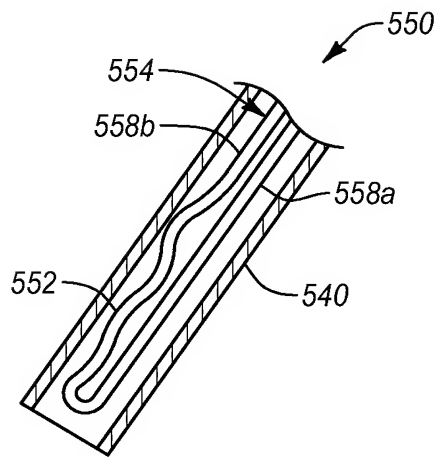


Fig. 5A

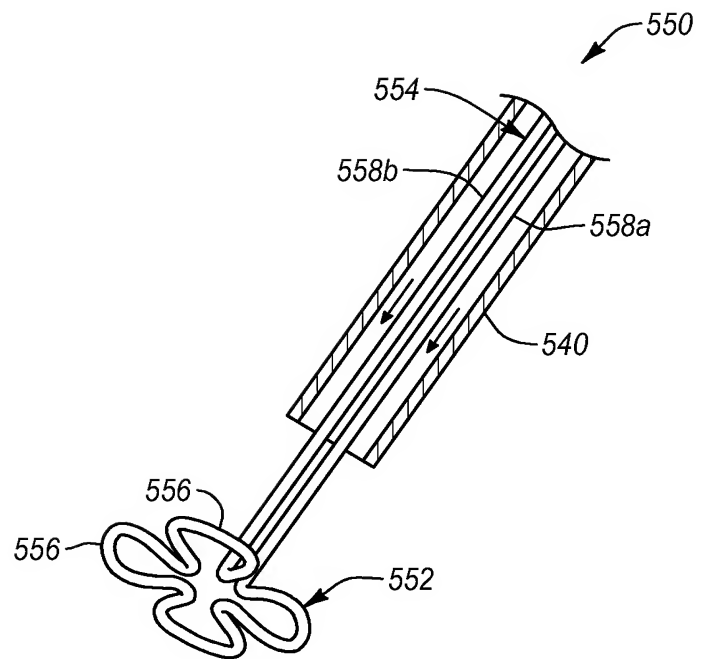


Fig. 5B

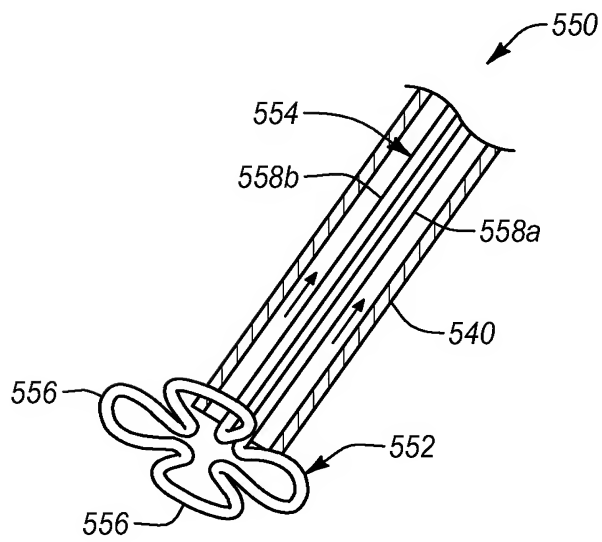


Fig. 5C

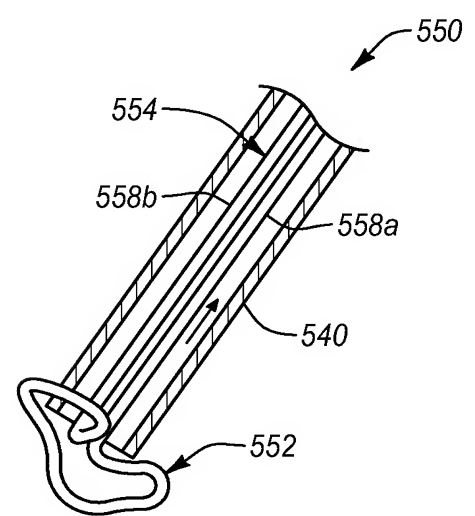


Fig. 5D

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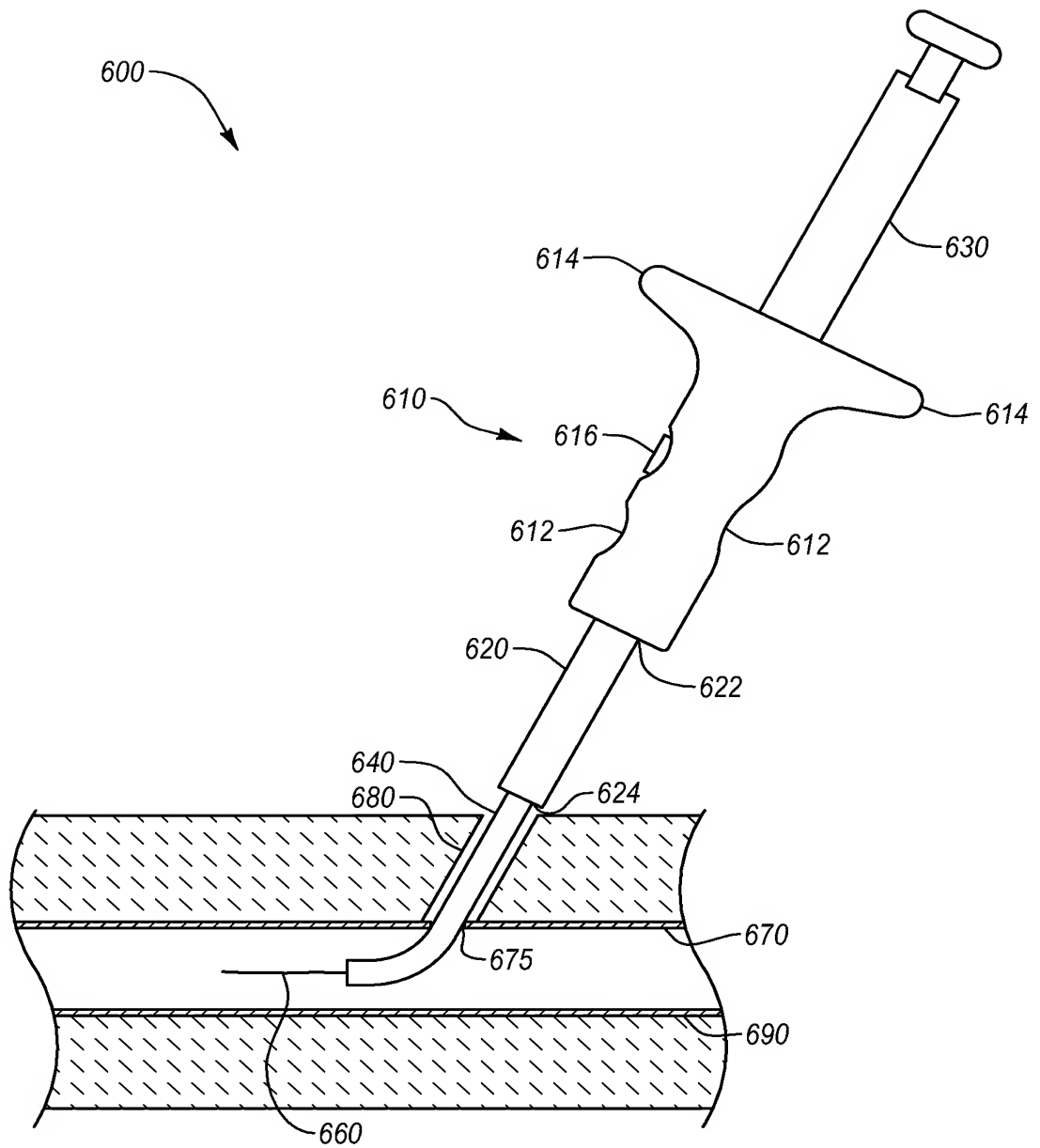


Fig. 6A

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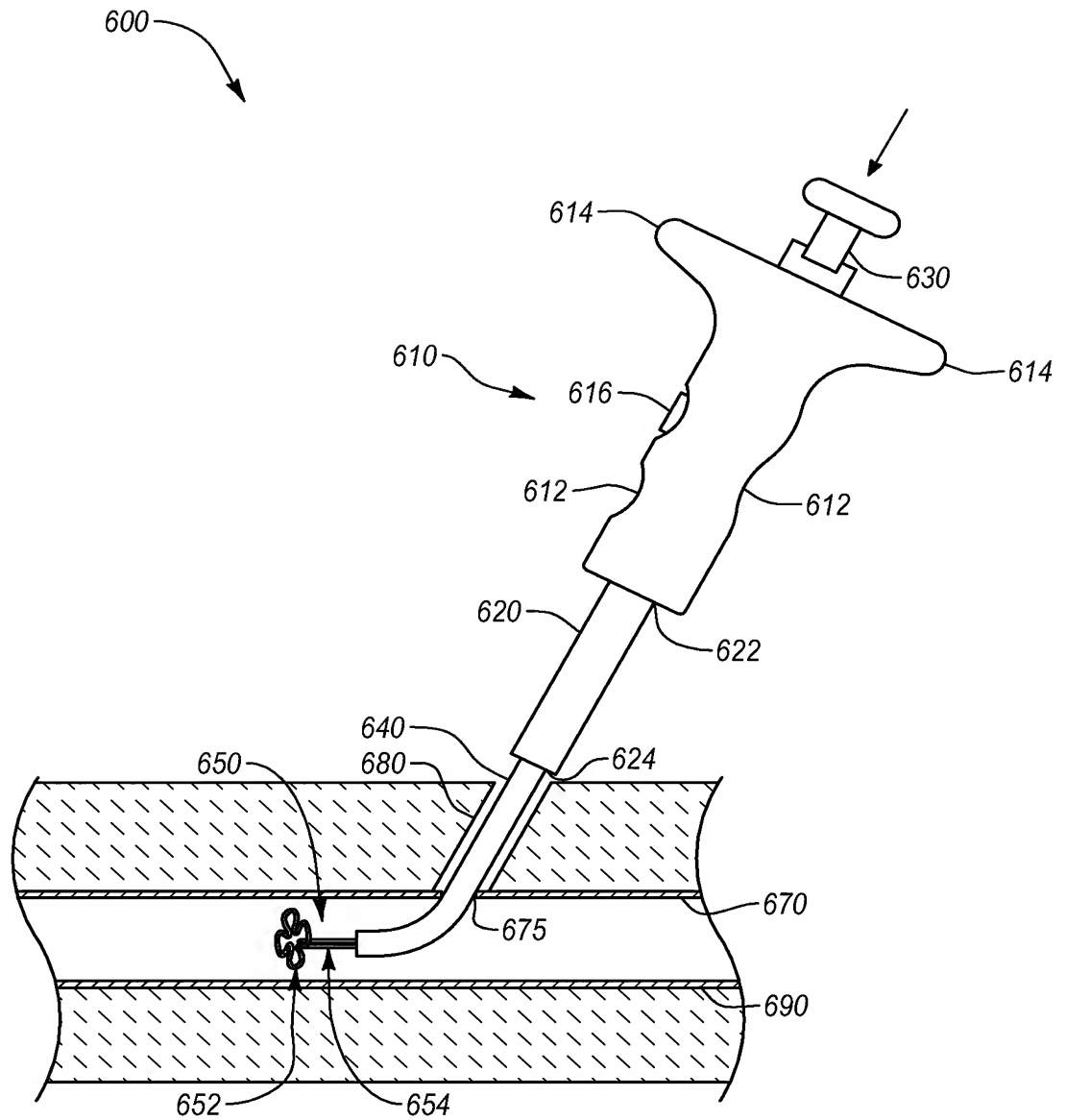


Fig. 6B

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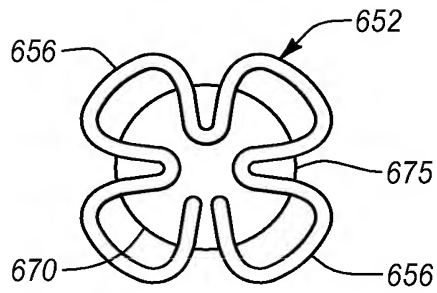


Fig. 6C'

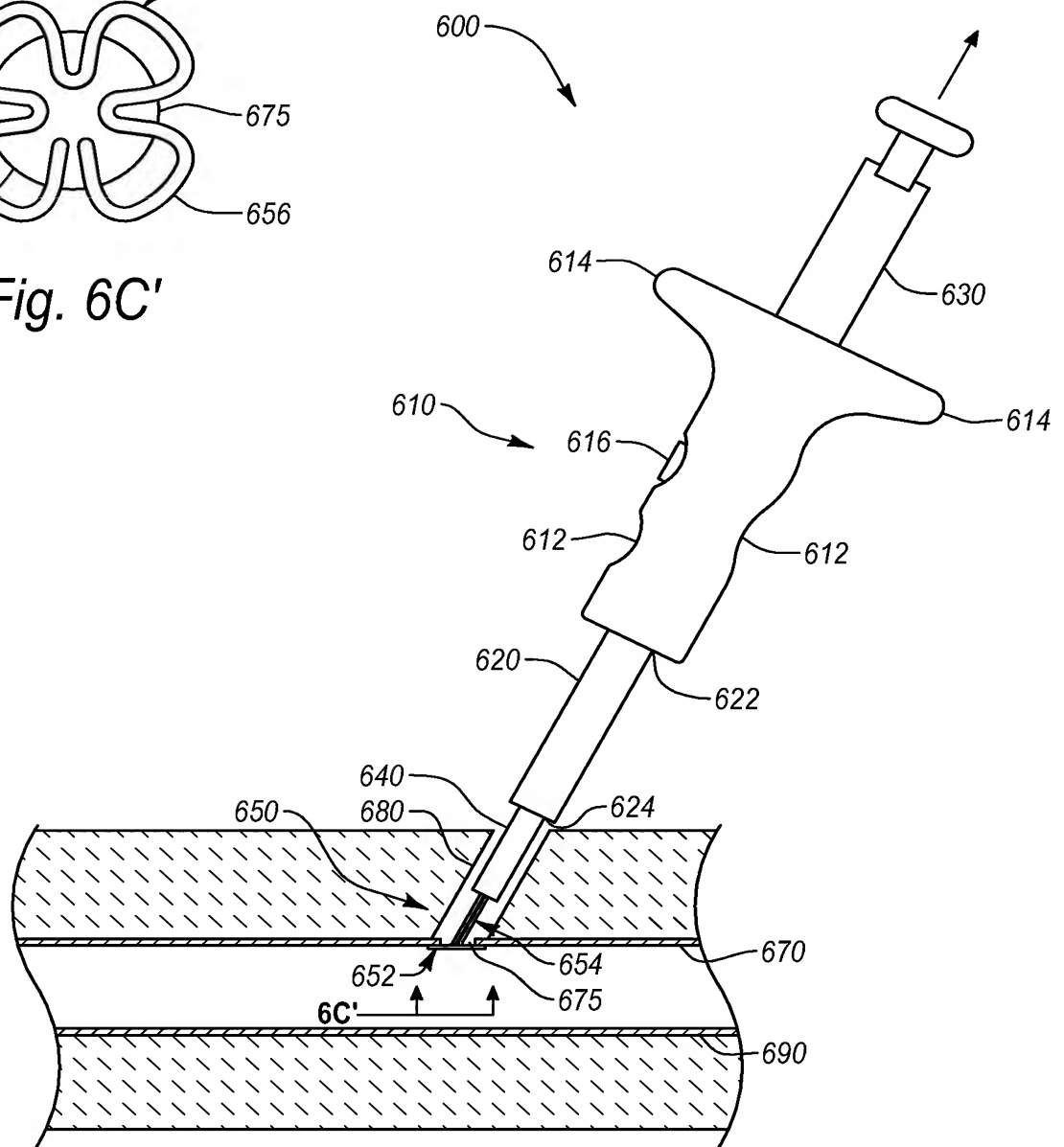
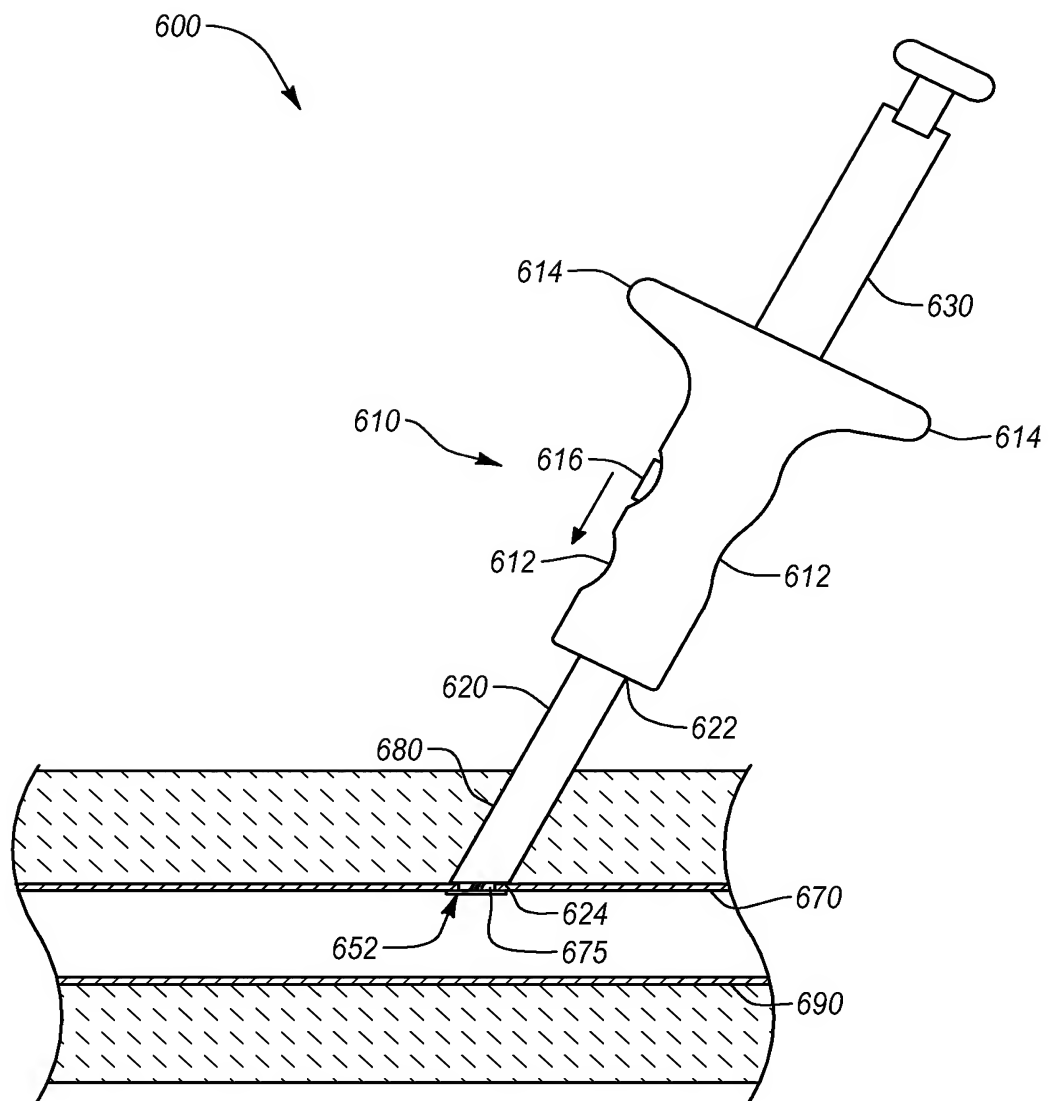
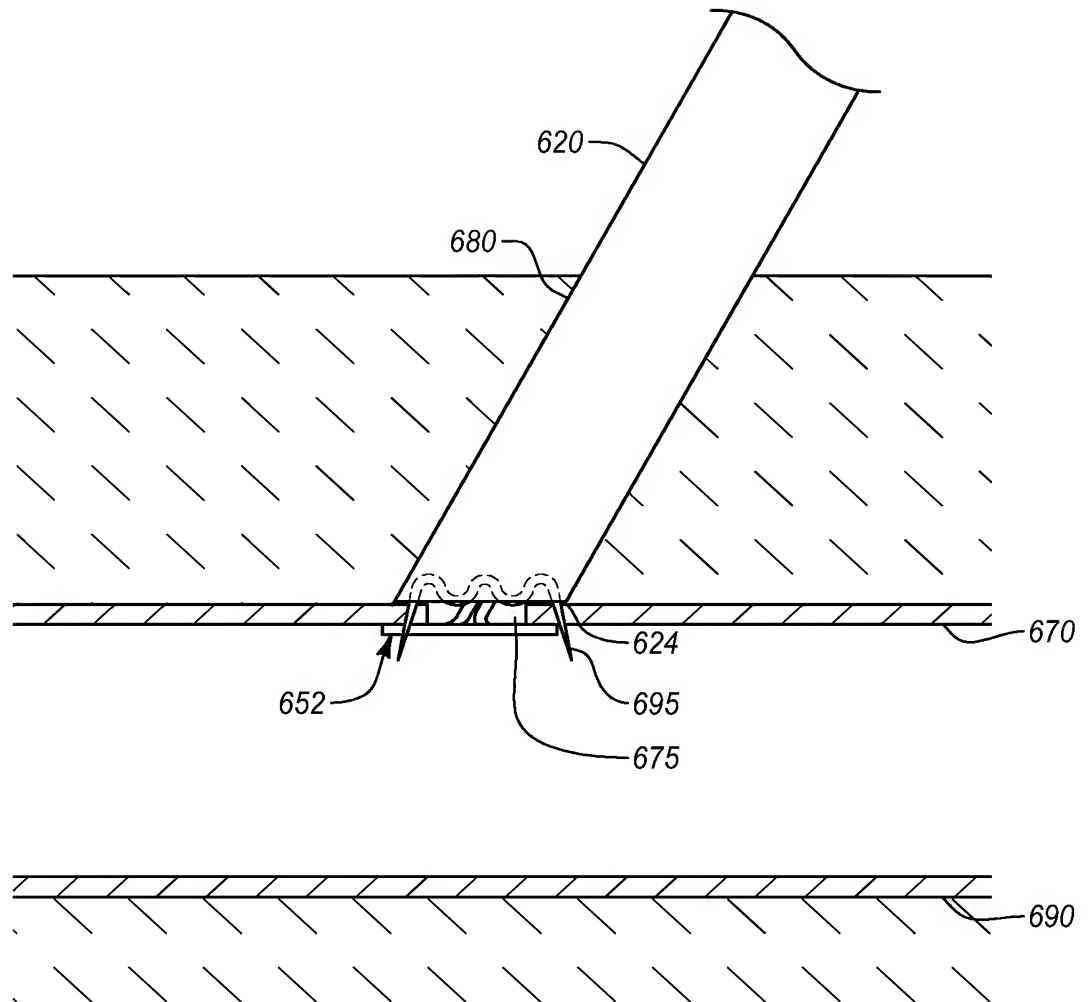


Fig. 6C

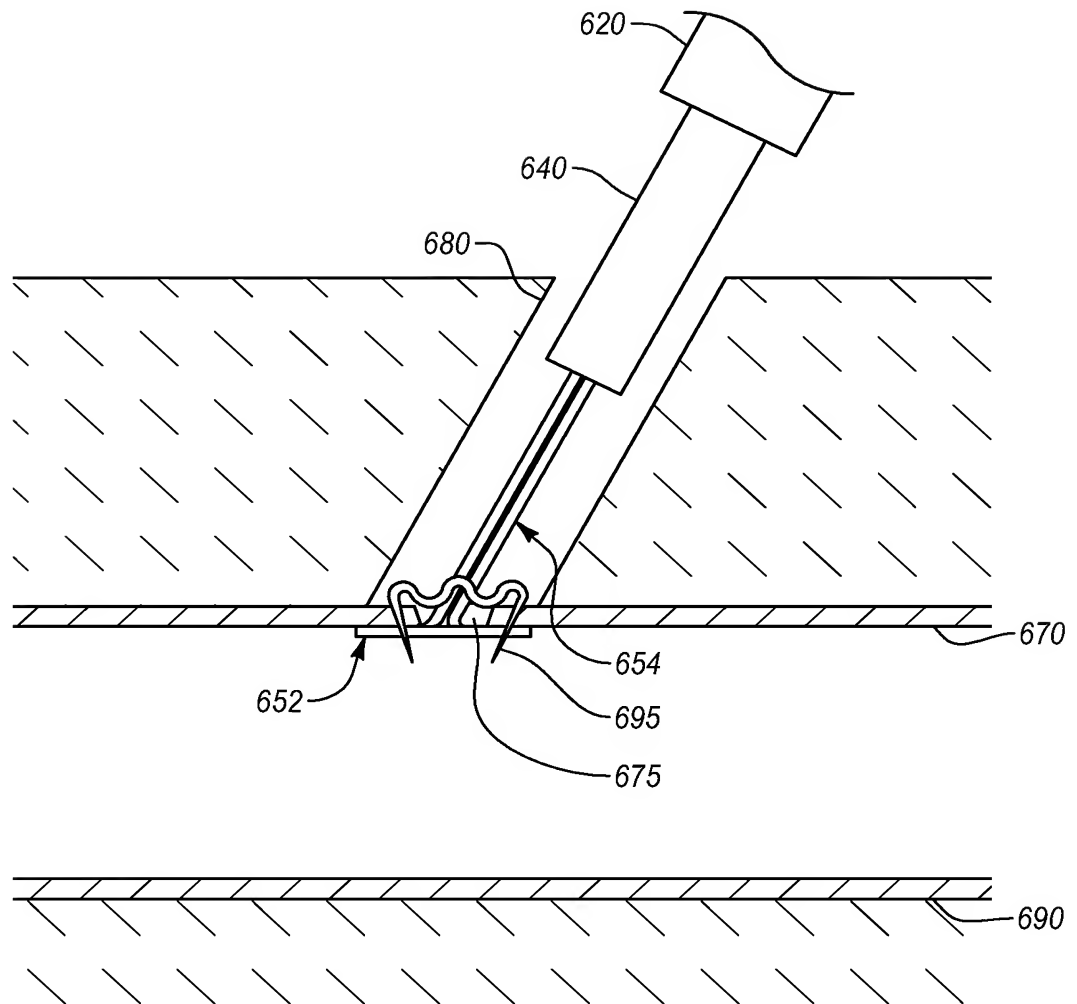
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*Fig. 6D*

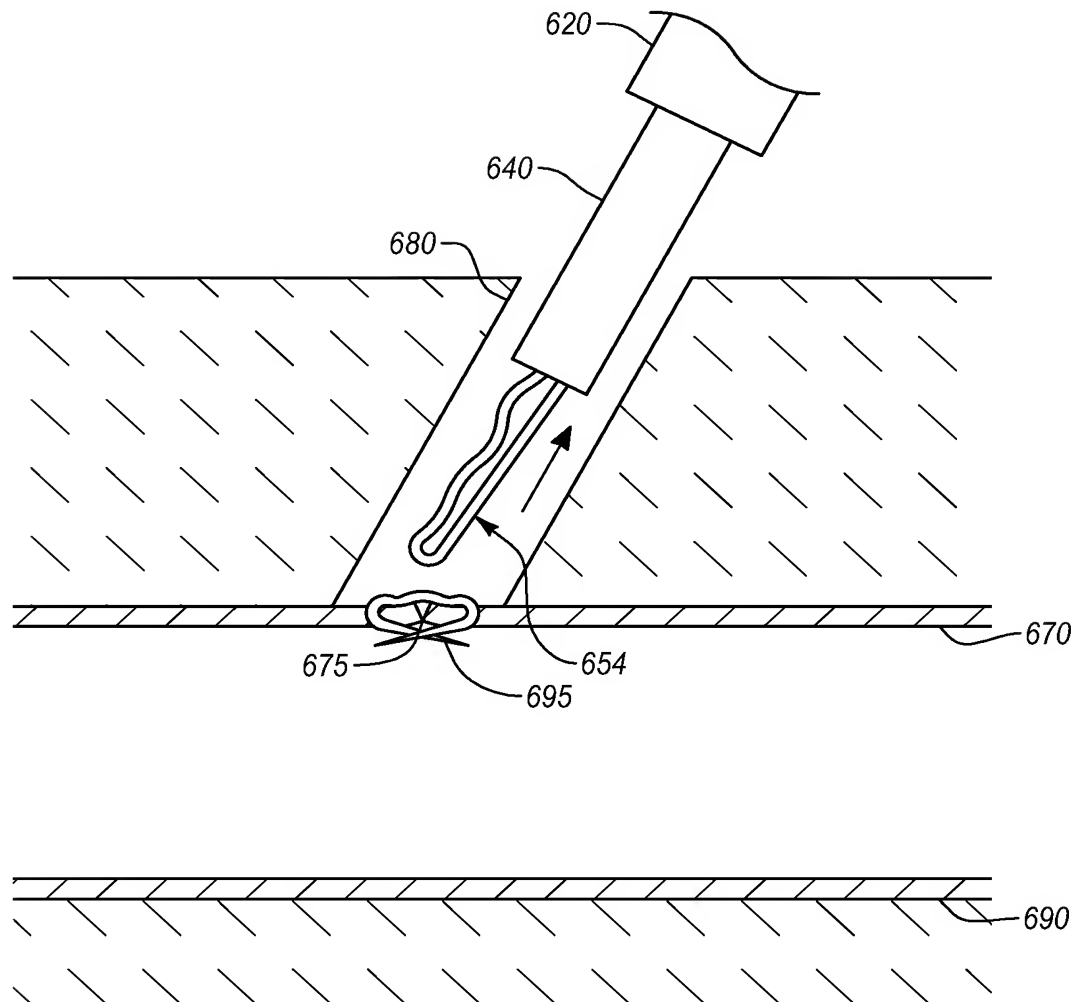
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*Fig. 6E*

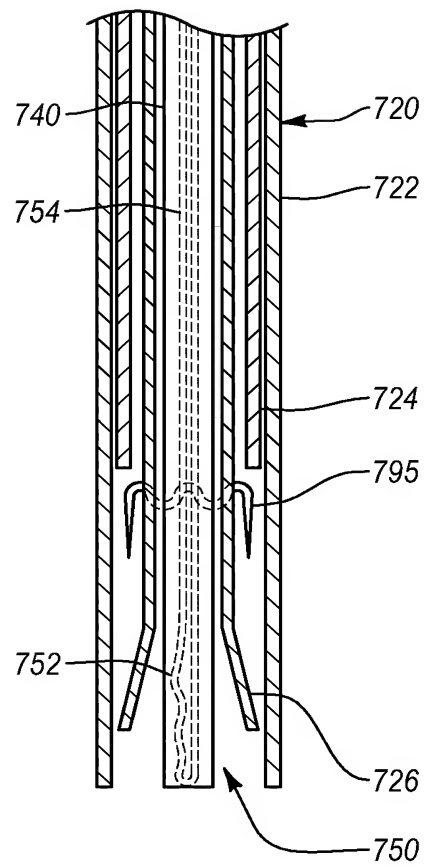
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*Fig. 6F*

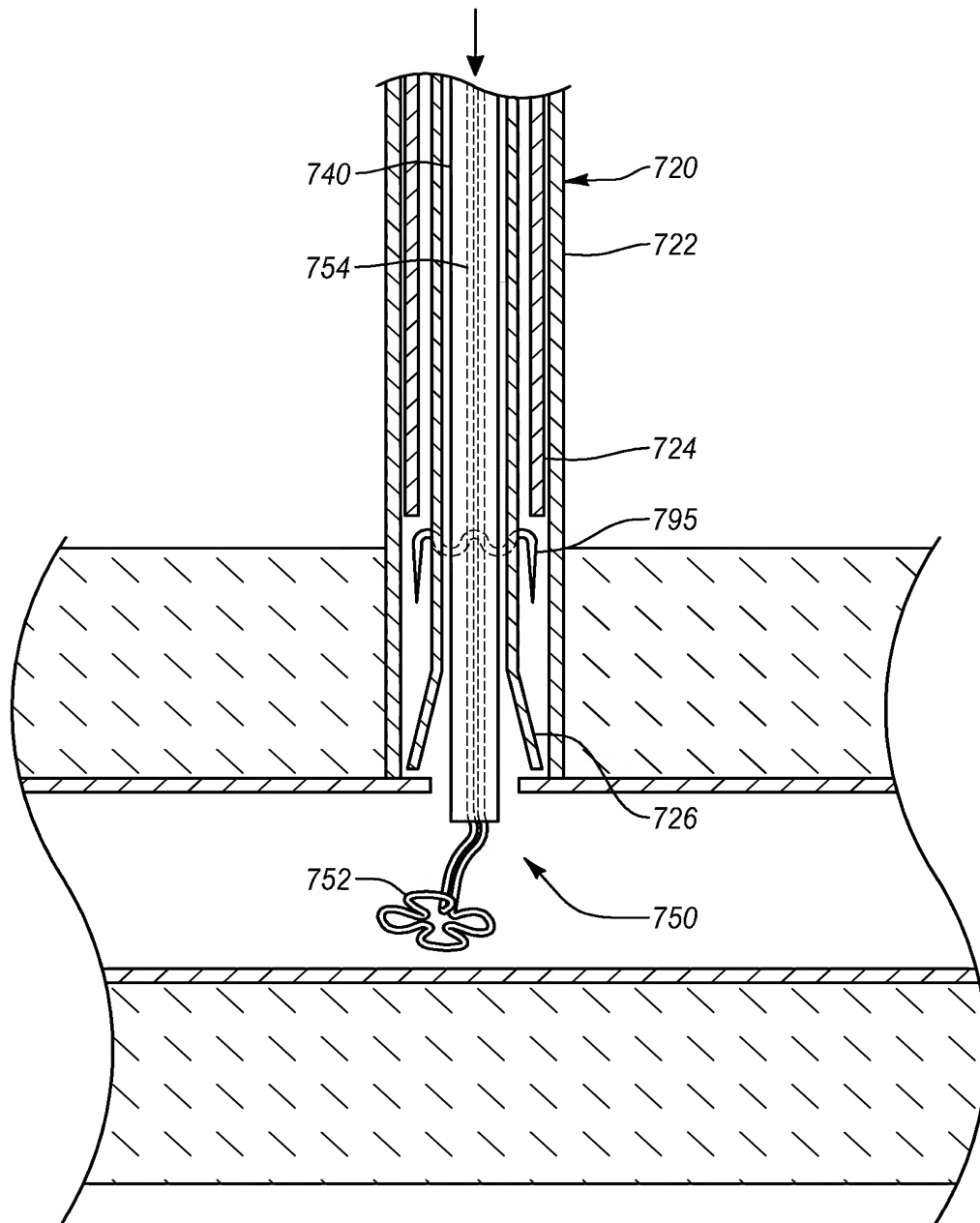
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*Fig. 6G*

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*Fig. 7A*

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*Fig. 7B*

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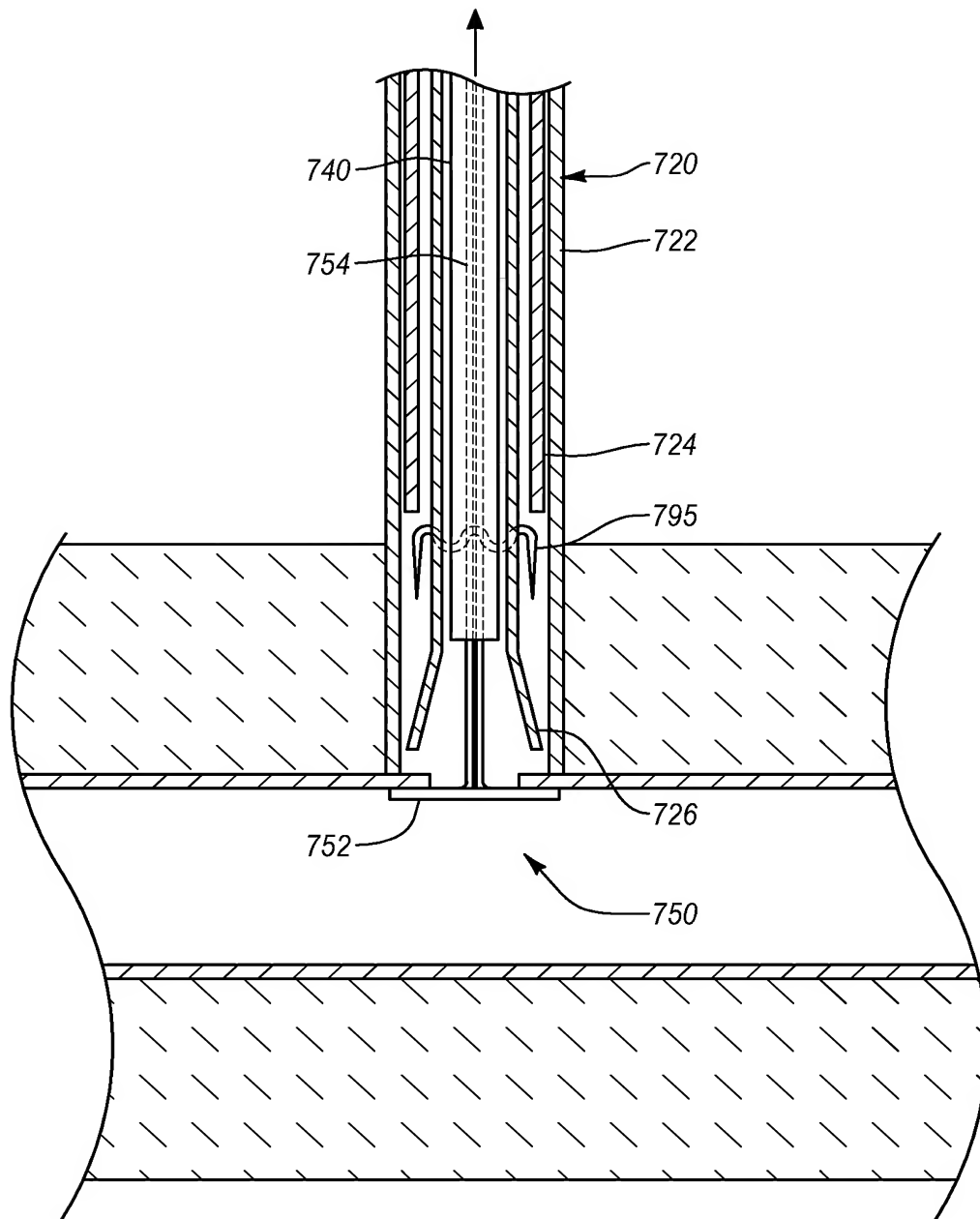


Fig. 7C

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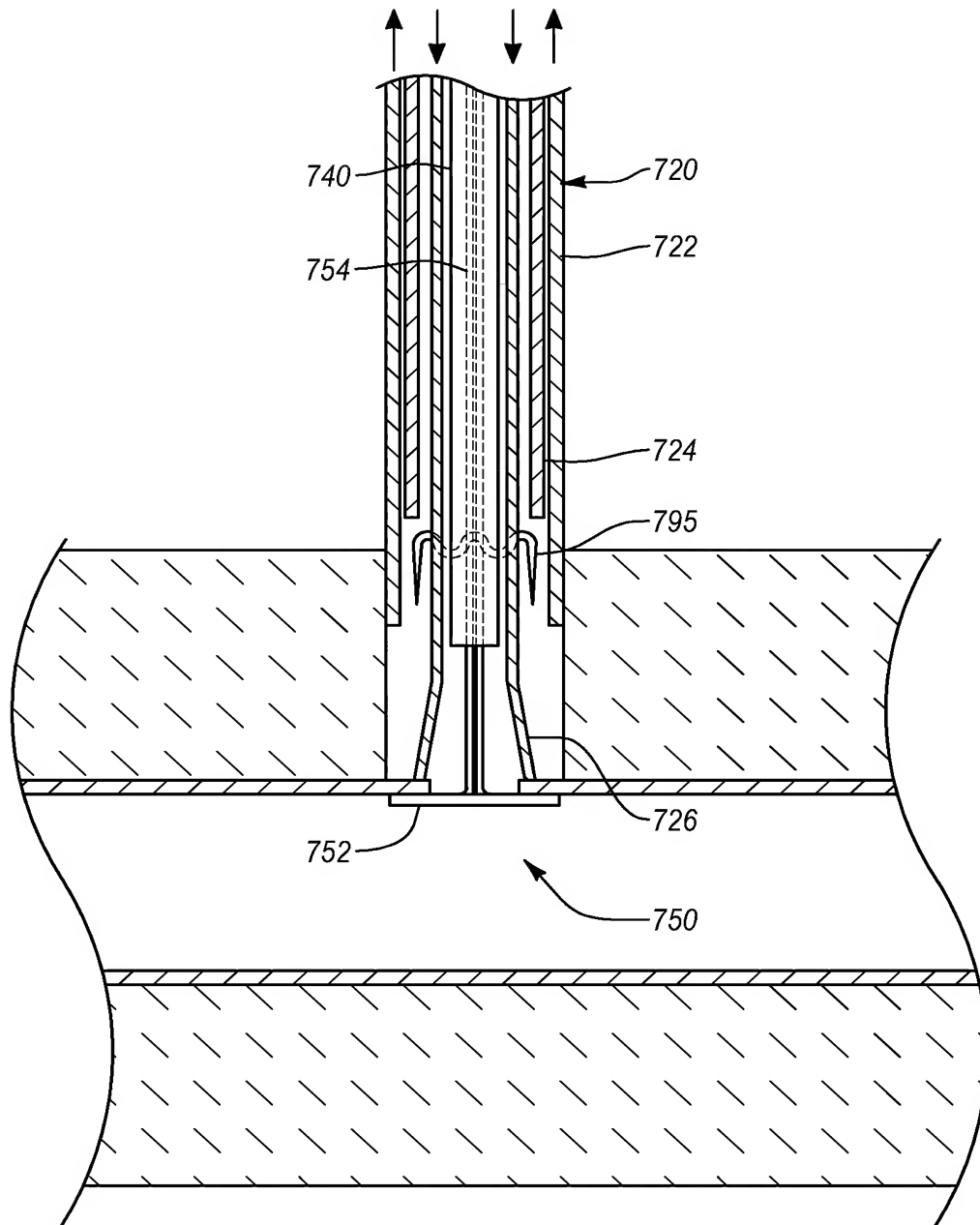


Fig. 7D

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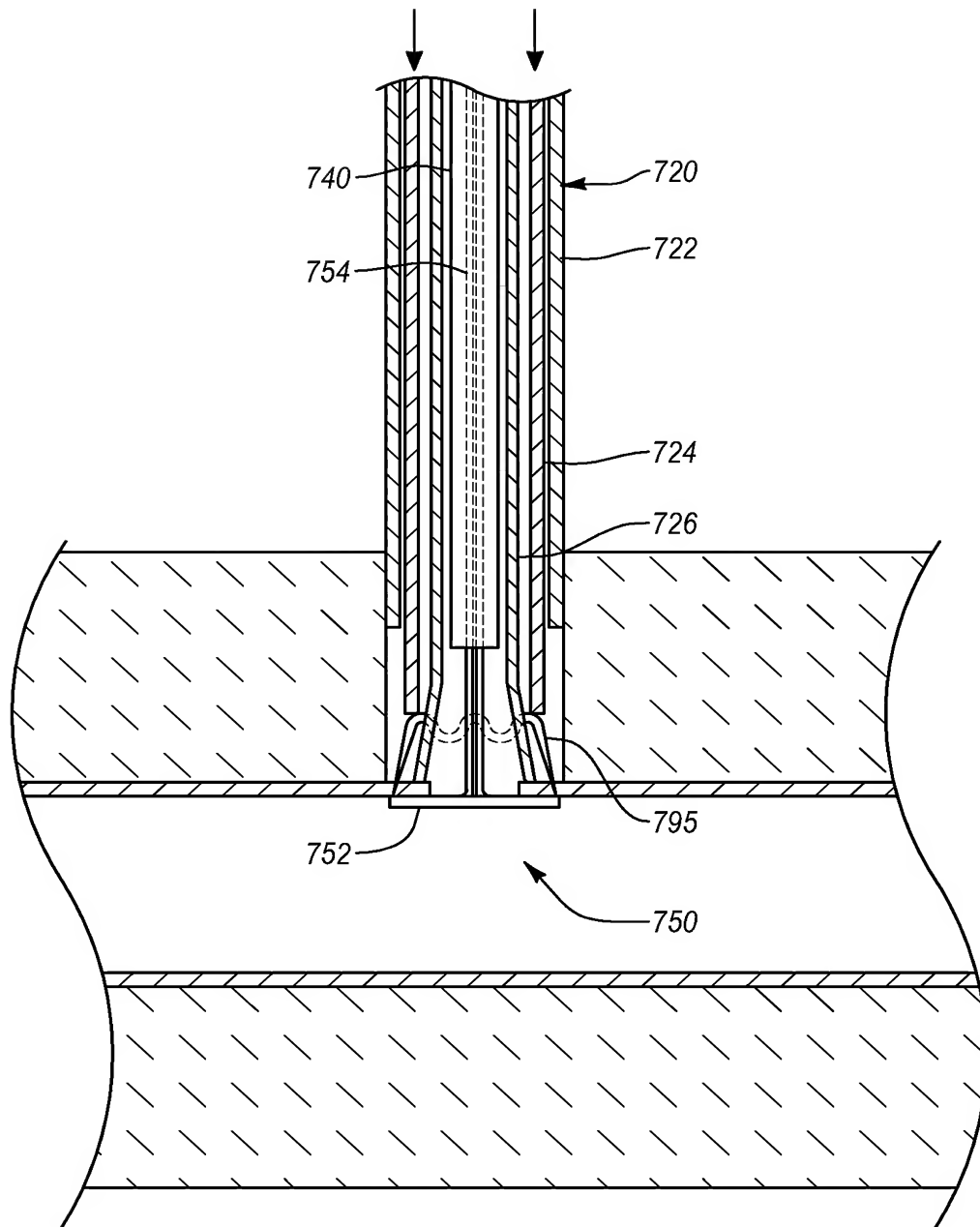


Fig. 7E

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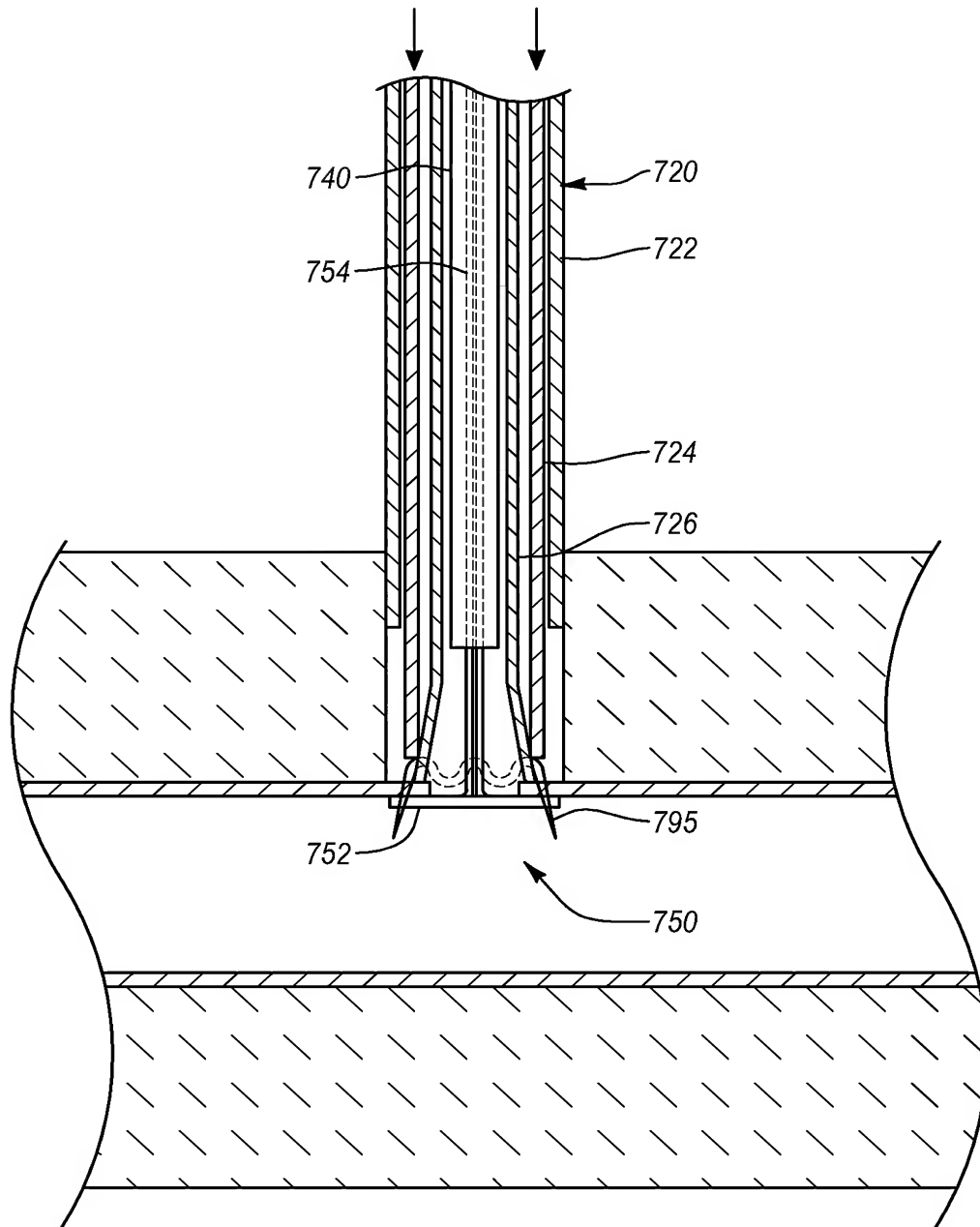


Fig. 7F

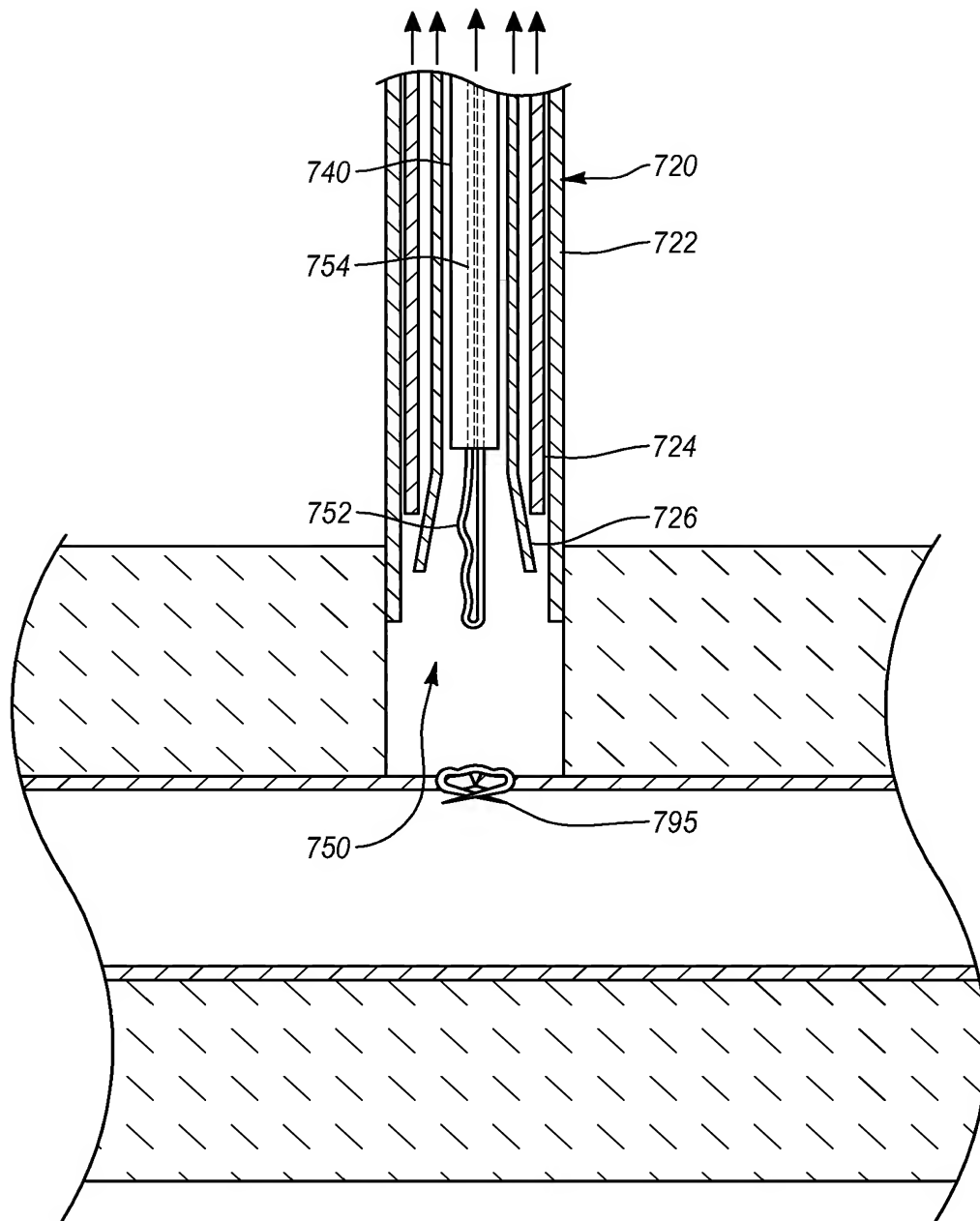


Fig. 7G

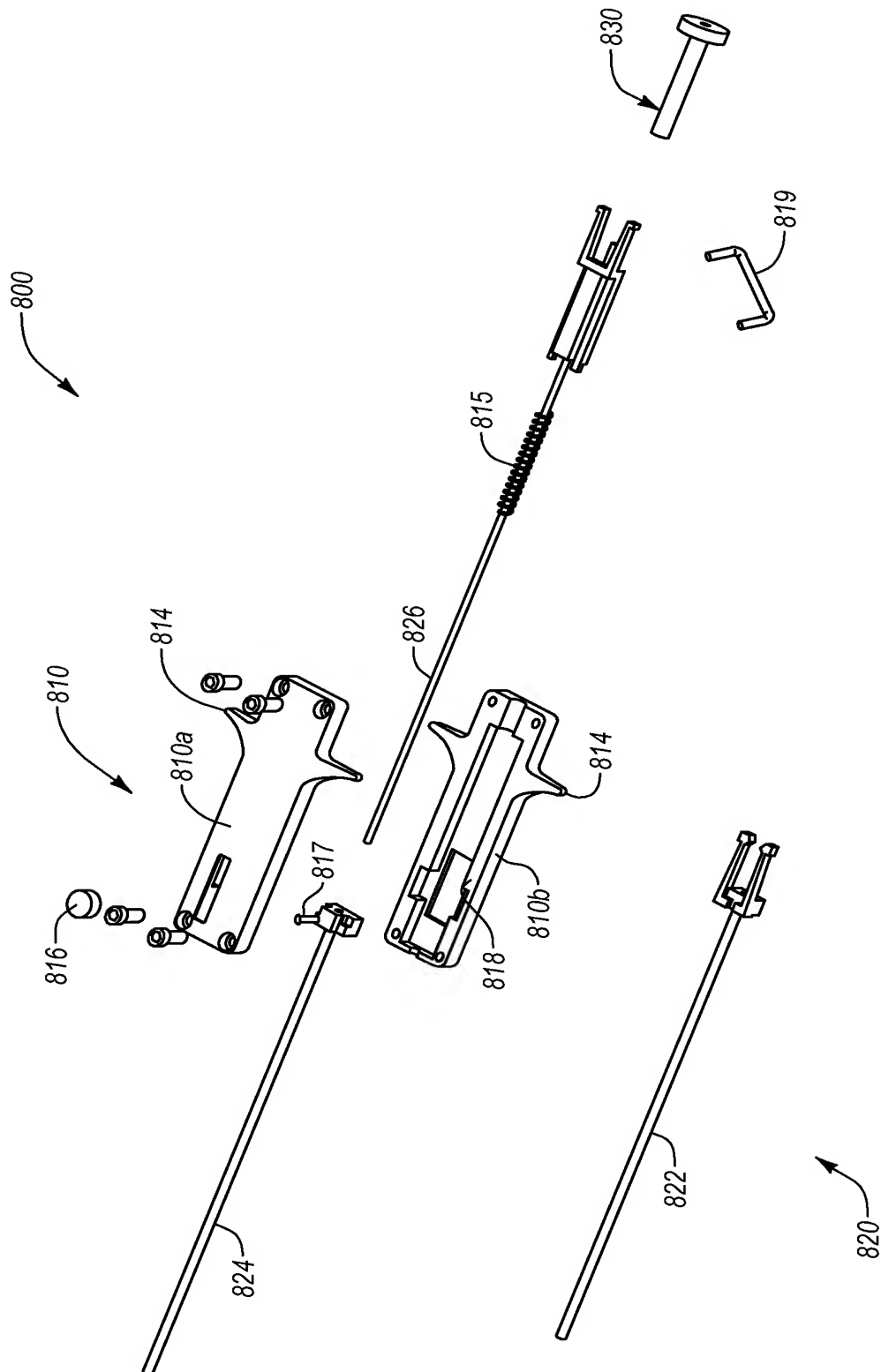


Fig. 8